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When Toning Shoes Strengthen Nothing More than Likelihood of Lawsuit: Why the Federal Trade Commission Needs Guidelines Regarding Proper Substantiation of Fitness Advertisements

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WHEN TONING SHOES STRENGTHEN NOTHING MORE THAN LIKELIHOOD OF LAWSUIT: WHY THE FEDERAL TRADE COMMISSION NEEDS GUIDELINES REGARDING PROPER SUBSTANTIATION OF FITNESS ADVERTISEMENTS

"*Consumers expected to get a workout, not worked over.*"[1]
– David Vladeck, Director of the FTC's Bureau of Consumer Protection

I. Off and Running: The Billion Dollar Toning Shoe Industry

With over one-third of adult Americans classified as obese, and an additional third of adult Americans classified as overweight, it should come as no surprise that U.S. consumers have been reported to spend over $30 billion per year on weight loss products.[2] Scientists and health professionals assert that the most successful way to lose weight and maintain a healthy lifestyle is through a combination of balanced nutrition and regular physical activity.[3] Despite this, it is also no surprise that manufacturers and retailers of fitness and diet products are continually developing and marketing

1. Natalie Zmuda, *Reebok Agrees to $25M Settlement Over Butt-Shaping Shoes*, Adver. Age (Sept. 28, 2011), http://adage.com/article/news/ftc-calls-butt-shaping-shoes-bogus-reebok-stands-claims/230082/ [hereinafter Zmuda I] (reporting comments of FTC official following Reebok decision).

2. *See Obesity and Overweight*, Ctrs. for Disease Control & Prevention, http://www.cdc.gov/nchs/fastats/overwt.htm (last updated Nov. 17, 2011) (collecting statistics on percentages of overweight and obese Americans); Fed. Trade Comm'n, Weight-Loss Advertising: An Analysis of Current Trends iv (2002) [hereinafter FTC Weight-Loss Advertising Report], *available at* http://www.ftc.gov/bcp/reports/weightloss.pdf (reporting amount of money spent on weight loss "products and services"). *See also* Melissa McNamara, *Diet Industry is Big Business*, CBS News (Feb. 11, 2009, 5:40 PM), http://www.cbsnews.com/stories/2006/12/01/eveningnews/main2222867.shtml ("Americans spend about $35 billion a year on weight-loss products.").

3. *See, e.g.*, *Diet and Exercise*, Mayo Clinic, http://www.mayoclinic.com/health/weight-loss/MY00432/DSECTION=diet-and-exercise (last visited Jan. 24, 2012) (recommending "healthy, lower calorie meals" and "being more active"); *Dietary Guidelines for Americans, 2010*, U.S. Dep't of Health & Human Servs., http://health.gov/dietaryguidelines/2010.asp (last visited Jan. 24, 2012) (summarizing main points from HHS & USDA report recommending healthy behaviors for Americans).

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products that claim to maximize weight loss but minimize the effort that users must expend to achieve their desired results.[4]

A recent phenomenon in weight loss products is the rise of "toning shoes": footwear with an uneven sole designed to create instability for the wearer.[5] Manufacturers assert that the instability and soft sole surface, integrating "balance ball technology," forces leg muscles to work harder than they would with normal shoes and therefore tones the lower body.[6] Since 2008, the toning shoe segment of the athletic footwear industry has exploded with consumers, the vast majority of which are women.[7] In 2008, overall sales of toning shoes generated $50 million; in 2010, sales netted $1.1 billion.[8]

As of March 2011, the Skechers shoe company dominated the toning shoe market with 60 percent of the market share; Reebok, a distant second, controlled 33 percent of the market share.[9] The toning shoe industry has helped itself by gathering a large number of celebrity endorsements to grace its ads: one Reebok advertise-

4. *See* FTC WEIGHT-LOSS ADVERTISING REPORT, *supra* note 2, at vii-x (compiling and describing types of advertising techniques in weight loss products and services). R

5. *See* Andrew Martin & Anahad O'Connor, *Reebok to Pay $25 Million Over Toning Shoe Claims*, N.Y. TIMES, Sept. 29, 2011, at B1, *available at* http://www.nytimes.com/2011/09/29/business/reebok-to-pay-in-settlement-over-health-claims.html?pagewanted=1&_r=1 (attributing development of Reebok toning shoes to former NASA engineer interested in using balance ball technology).

6. *See id.* (referencing Reebok's main pitch of "balance ball-inspired technology" as means of creating instability leading to better workout); *see also* Natalie Zmuda, *Will Toning Shoes Be the Next Big Fitness Craze?*, ADVER. AGE (July 15, 2009), http://adage.com/article/news/marketing-toning-shoes-big-footwear-craze/137949/ [hereinafter Zmuda II] (referencing role of toning shoes as soft walking surface, forcing wearer to use muscles not used while walking on normal hard surfaces).

7. *See* Michael McCarthy, *A Revolutionary Sneaker, or Overhyped Gimmick?*, USA TODAY, June 30, 2010, at 1A, *available at* http://www.usatoday.com/sports/2010-06-30-toning-shoes_N.htm (quoting SportsOneSource sneaker analyst stating that toning shoe consumers were 90 percent female). Additionally, consumers are often women who spend much of the day on their feet, including teachers, nurses, stylists, and restaurant servers. *See id.* (noting characteristics of toning shoe clientele).

8. *See* Martin & O'Connor, *supra* note 5, at B1 (citing toning shoe sales statistics). Athletic footwear overall generates approximately $17 billion per year. *See* McCarthy, *supra* note 7, at 1A (providing total industry figures). R R

9. *See* Zmuda I, *supra* note 1 (discussing market share statistics for toning shoe sales). Notably, fitness giant Nike has refused to develop or sell toning shoes, asserting that those shoes do not fit the company's model for performance-based fitness products. *See* Jeremy Mullman, *Nike Women's Biz Gets Pounded as Toning Footwear Kicks Butt*, ADVER. AGE, June 7, 2010, at 1, *available at* http://adage.com/article/news/nike-women-s-biz-pounded-toning-footwear-kicks-butt/144289/ (quoting Nike spokesman: "Unlike today's toning products, we won't ask the consumer to compromise on stability, flexibility or any other key performance characteristics as they train."). R

ment featured supermodel Helena Christensen entirely nude except for her Reebok EasyTone sneakers.[10] To increase male interest in toning shoes, Skechers recruited a number of retired professional athletes – including Joe Montana, Wayne Gretzky, Karl Malone, and Kareem Abdul-Jabbar – for its Shape-ups toning shoes advertisements.[11]

Reebok, a popular name in women's fitness gear since the 1980s aerobics craze, sold more than five million pairs of its EasyTone toning shoes in 2010 in the United States (an increase from fewer than one million in 2009), with shoes priced at $100 or more per pair.[12] Unfortunately for Reebok, however, in late 2011 the company became subject to a Federal Trade Commission (FTC) complaint alleging "unfair or deceptive acts or practices in or affecting commerce."[13] The FTC asserted in the complaint that Reebok's print and television marketing campaign (which cost the company more than $64 million for the U.S. alone since 2009) made unsubstantiated health claims about its EasyTone products.[14] Reebok settled the lawsuit, and the company was forced to pay $25 million to

10. *See Helena Christensen Poses Naked to Advertise Reebok. . . But Who's Looking at the Trainers?*, DAILY MAIL (May 1, 2010), http://www.dailymail.co.uk/tvshowbiz/article-1270226/Helena-Christensen-poses-naked-advertise-Reebok—whos-looking-trainers.html (describing Christensen advertisement and providing photo); *see also* Andrew Hampp, *Skechers Returns to Super Bowl, Now With Kim Kardashian and a Plan*, ADVER. AGE (Jan. 25, 2011), http://adage.com/article/special-report-super-bowl/skechers-returns-super-bowl-kim-kardashian/148482/ (describing details of Skechers Super Bowl toning shoe advertisement featuring television personality Kim Kardashian).

11. *See* John Brilliant, *Wayne Gretzky Shapes Up With Sketchers Endorsement*, COUNTERKICKS (Jan. 11, 2011), http://counterkicks.com/2011/01/11/wayne-gretzky-shapes-up-with-skechers-endorsement/ (listing celebrity endorsements of Sketchers toning shoes and noting Gretzky's signing with company); *see also* McCarthy, *supra* note 7, at 1A (referencing Montana endorsement as effort to attract men to toning shoes). R

12. *See* Natalie Zmuda, *Reebok EasyTone*, ADVER. AGE, Nov. 15, 2010, at 30, *available at* http://adage.com/article/print-edition/reebok-easytone-america-s-hottest-brands-2010/147068/ [hereinafter Zmuda III] (alluding to Reebok's role in popularizing aerobics in 1980s); Martin & O'Connor, *supra* note 5, at B1 (citing statistics of sales numbers and shoe prices). R

13. *See* Complaint for Permanent Injunction and Other Equitable Relief at 8, FTC v. Reebok Int'l Ltd., 1:11-cv-01046-DCN (N.D. Ohio Sept. 28, 2011), *available at* http://www.ftc.gov/os/caselist/1023070/110928reebokcmpt.pdf [hereinafter FTC Complaint] (alleging violation of FTC Act regarding unfair and deceptive advertising).

14. *See id.* at 9-10 (detailing claims regarding Reebok advertising and failure to substantiate health benefits); *see also* Zmuda I, *supra* note 1 (reporting on Reebok EasyTone advertising budget for U.S. promotion: $23 million in 2009, $31 million in 2010, and $10 million in first half of 2011). R

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its affected customers and was also prohibited from claiming health and exercise benefits without acceptable scientific evidence.[15]

The FTC has the regulatory authority to prohibit advertisers from making false or deceptive claims, including claims that are not properly substantiated by scientific evidence.[16] The FTC enforces advertising laws by conducting internal agency investigations as well as bringing civil claims against advertisers in federal district court, seeking injunctions to stop the dissemination of ads and winning monetary relief for consumers.[17] In many situations regarding unsubstantiated advertisements, FTC investigations and lawsuits end in consent orders in which the retailers agree to stop using the offending advertisements and pay a penalty in exchange for the FTC agreeing to drop the suit.[18] Although the agency has general guidelines regarding the legal standard that advertisers must follow, it has not issued official guidance detailing how retailers can adequately substantiate claims.[19] Coupled with the fact that few fitness substantiation disputes reach trial, this lack of guidance creates a significant hole in the FTC's regulatory enforcement program designed to ensure that consumers are protected from unsubstantiated fitness products.[20]

This Comment will evaluate the FTC's settlement with Reebok regarding unsubstantiated claims in fitness and health advertising and discuss how this settlement paves the way for the FTC to prohibit more effectively other unsubstantiated fitness and performance claims. Section II will discuss Reebok's EasyTone advertising campaign and the fitness-related claims the company made about

15. *See* Martin & O'Connor, *supra* note 5, at B1 (noting details of Reebok's settling lawsuit with FTC). R

16. *See* In re Pfizer Inc., 81 F.T.C. 23, 26 (1972) (asserting Commission's authority to protect consumers from unsubstantiated claims).

17. *See generally* 15 U.S.C. § 45 (2006) (providing variety of ways in which FTC can enforce advertising laws).

18. *See* Diet Center et al., 5 Trade Reg. Rep. (CCH) ¶23,357, ¶23,357 (1993) (stating how FTC disputes are often resolved through individual consent orders).

19. *See FTC Policy Statement Regarding Advertising Substantiation*, FED. TRADE COMM'N (1984), http://ftc.gov/bcp/guides/ad3subst.htm [hereinafter *FTC Policy Statement*] (stating agency's legal basis to enforce adequate substantiation); *Advertising Claims for Dietary Supplements: Denial for Petition of Rulemaking*, FED. TRADE COMM'N (Nov. 30, 2000), http://www.ftc.gov/os/2000/12/dietletter.htm (acknowledging lack of industry-wide official standards).

20. *See Reebok to Pay $25 Million in Customer Refunds To Settle FTC Charges of Deceptive Advertising of EasyTone and RunTone Shoes*, FED. TRADE COMM'N (Sept. 28, 2011), http://www.ftc.gov/opa/2011/09/reebok.shtm (citing comments from FTC officials about agency's role in protecting consumers from fitness products that claim disputed results).

its toning shoe products.[21] Section III will detail how Reebok encountered resistance to its toning shoe products, including the FTC complaint against the company and the details of Reebok's final settlement with the FTC.[22] Section IV will consider the FTC's regulatory authority to ensure that advertisements are adequately substantiated by scientific evidence.[23] Section V will discuss why the FTC needs detailed substantiation guidelines for fitness products in order to better protect consumers.[24] Section VI will suggest what the agency should include in the proposed fitness substantiation guidelines to assist advertisers in making properly substantiated claims.[25] Finally, Section VII will summarize how FTC substantiation standards following the Reebok decision can ensure quality fitness advertising campaigns and reinforce consumer protection efforts.[26]

II. 'MAKE YOUR BOOBS JEALOUS': REEBOK'S TONING SHOE PRODUCT LINE AND ADVERTISING CAMPAIGN

The footwear at the center of Reebok's dispute with the FTC includes Reebok's line of toning footwear marketed for different purposes: EasyTone (for "everyday activities"), TrainTone (for fitness classes and training exercises), and JumpTone (for men).[27] Most of the disputed advertisements focus on the central EasyTone walking shoe, which is manufactured for and marketed to women.[28] Reebok also sells a line of EasyTone apparel including pants, shorts, shirts, and tank tops that claim to have resistance bands within the fabric to tone muscles and fix posture problems.[29] According to

21. For a discussion of Reebok's EasyTone advertising campaign, see *infra* notes 27-43 and accompanying text. R

22. For a discussion of the FTC complaint and settled consent order, see *infra* notes 44-93 and accompanying text. R

23. For a discussion of the FTC's enforcement history in weight loss products, see *infra* notes 94-159 and accompanying text. R

24. For a discussion of what the FTC can establish to improve its enforcement authority in substantiating claims, see *infra* notes 160-232 and accompanying text. R

25. For a discussion of what the FTC should include in the proposed fitness substantiation guidelines, see *infra* notes 233-284 and accompanying text. R

26. For a discussion of why the Reebok decision should prompt substantiation guidelines to help consumers, see *infra* notes 285-303 and accompanying text. R

27. *See* FTC Complaint, *supra* note 13, at 4-5 (listing Reebok products that FTC identified as having advertising discrepancies). Reebok also sells SimplyTone discount walking shoes and EasyTone flip-flop sandals. *See id.* at 3-4 (describing remainder of Reebok toning product lines). R

28. *See id.* at 4 (explaining nature of specific EasyTone shoe).

29. *See* Zmuda III, *supra* note 12, at 30 (discussing attributes of EasyTone clothing line to "tone muscles and improve posture"). R

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the FTC's complaint, Reebok has been manufacturing the EasyTone product line since at least May 2009.[30]

Reebok's RunTone shoe line also came under FTC scrutiny based on its advertising campaign.[31] RunTone toning shoes have a similar design to EasyTone shoes but are marketed for jogging or running.[32] Both EasyTone and RunTone shoes cost approximately $100 per pair and can be purchased either directly from Reebok (online or at a physical location), or at third party sporting goods or specialty shoe stores.[33] Reebok's entire line of toning products is sometimes referred to as "ReeTone."[34]

Reebok's EasyTone promotions have been available to the public through print advertisements in national newspapers and magazines; through Internet websites, including Reebok's own website as well as social networking sites Facebook and Twitter; and on television commercials broadcasted on major networks.[35] Many of the EasyTone ads, both in print and video, feature scantily clad and toned women who may or may not be wearing toning shoes in the advertisement.[36] For example, in one of the television ads, a woman's bra-covered breasts "talk" to each other about the impressive appearance of the woman's rear thanks to EasyTone shoes.[37] In

30. *See* FTC Complaint, *supra* note 13, at 3 (listing manufacturing duration of EasyTone products); *see also* Zmuda II, *supra* note 6 (referencing EasyTone release date as within first half of 2009). R R

31. *See* FTC Complaint, *supra* note 13, at 7-8 (describing RunTone shoes as part of covered products). R

32. *See id.* (explaining shoe's use and advertising claims similar to EasyTone).

33. *See id.* at 3-4 (specifying locations at which consumers can purchase EasyTone shoes, including third parties such as Dick's Sporting Goods, Famous Footwear, and Nordstrom).

34. *See id.* at 5 (summarizing Reebok product line).

35. *See id.* (listing summary of media through which Reebok has advertised EasyTone products).

36. *See id.* ("The advertisements frequently display women who are very toned, scantily-clad, and sometimes nude . . .").

37. *See* FTC Complaint, *supra* note 13, at 6 (describing television ad in which woman's "partially covered" breasts "speak[ ] to one another"). The dialogue is as follows: R

> Breast 1: Hey, did ya see? Nobody's staring at us anymore.
> Breast 2: Hmm, aren't we still hot?
> Breast 1: Totally! You know what? It's all because of that stupid butt down there.
> Breast 2: Yeah, stupid butt. Gets all the attention now.
> Breast 1: She's so tight now. So round. So pretty.
> Breast 2: And so stupid.
> Make your boobs jealous. With the shoe proven to tone your butt up to 28% more and your hamstrings and calves up to 11% more than regular sneakers. Reebok EasyTone. With balance ball inspired technology. Better legs and a better butt with every step.

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another television ad, a camera focuses in on a woman's shorts-covered backside as the woman is trying to talk to the camera about the shoes, and she admonishes the camera's holder for the inappropriate focus.[38] EasyTone and RunTone print ads are also known for featuring similarly fit and toned women wearing the shoes.[39]

Following the FTC intervention, Reebok left advertising agency DDB, which had spearheaded the EasyTone campaign since 2009, and returned to agency McGarryBowen, which had handled Reebok's advertising from 2004 to 2009.[40] Neither Reebok nor the ad agencies made public comments referencing the FTC decision as a reason for the switch.[41] In January 2012, Reebok launched its first advertising campaign including EasyTone products since the FTC settlement, a campaign distinct from the previous marketing strategies that led to the FTC action.[42] The new $50 million campaign, which endorses the overall Reebok brand as well as specific products (including EasyTone), is a worldwide promotion of the theme "the sport of fitness."[43]

III. EXERCISE SCIENTISTS AND THE FTC UPSET THE BALANCE ON 'BALANCE BALL TECHNOLOGY'

A. Scientist Concerns and the Advertising Industry's Self-Regulation

Even before the FTC filed its complaint against Reebok for unsubstantiated advertising claims, exercise scientists and physical

See id. (providing ad's spoken content in complaint); *see also* Hortense Smith, *"Make Your Boobs Jealous": Reebok's "EasyTone" Ad Campaign is an Epic Fail*, JEZEBEL (Nov. 9, 2009, 12:40 PM), http://jezebel.com/5410315/make-your-boobs-jealous-reeboks-easytone-ad-campaign-is-an-epic-fail (providing commentary and link to "Boobs" advertisement).

38. *See* FTC Complaint, *supra* note 13, at 5-6 (transcribing ad's dialogue and camera movements). R

39. *See id.* at 7-8 (explaining nature of EasyTone and RunTone ads); *see also Complaint Exhibits 3-7*, FED. TRADE COMM'N, http://www.ftc.gov/os/caselist/1023070/110928reebokexh3-7.pdf (last visited Jan. 28, 2011) (providing pictures of Reebok print ads).

40. *See* Rupal Parekh & Maureen Morrison, *Nearly Three Years After Breakup, Reebok Returns to McGarryBowen*, ADVER. AGE (Jan. 06, 2012), http://adage.com/article/agency-news/reebok-returns-mcgarrybowen/231952/ (discussing Reebok's history with McGarryBowen and split from DDB).

41. *See id.* (omitting mention of FTC settlement in article or PR comments).

42. *See* Stuart Elliot, *It's Winter, So Here Come the Sneaker Ads*, N.Y. TIMES (Jan. 13, 2012, 4:52 PM), http://mediadecoder.blogs.nytimes.com/2012/01/13/its-winter-so-here-come-the-sneaker-ads/ (detailing Reebok and other fitness companies' new winter advertising campaigns).

43. *See id.* (reporting that 2012 Reebok campaign spending is estimated at "more than" $50 million).

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therapists had begun considering whether toning shoes actually provided the benefits that manufacturers claimed.[44] In 2008, Reebok financed an unpublished study, later used to substantiate its claims, at the University of Delaware to test five participants' use of the toning shoes for a five-minute treadmill stint, compared to five minutes wearing normal walking shoes and five minutes wearing no shoes.[45] The study was conducted by a published exercise science researcher who placed electrodes on key muscle areas to test for increased muscle activation.[46] The researcher concluded that from the data collected, there was "compelling evidence for greater muscle activity," and the muscle activation data indicated that there was potential for the wearer to have a better workout while using the shoes.[47]

However, independent research studies cast doubt that toning shoes activated muscles in the ways that Reebok and other manufacturers claimed or provided wearers with a more strenuous workout than normal shoes.[48] The American Council on Exercise (a nonprofit certification and research organization) sponsored a toning shoe study conducted by University of Wisconsin-LaCrosse scientists that concluded that "none of the toning shoes showed statistically significant increases in either exercise response or muscle activation . . . ."[49] Those researchers found that use of toning shoes did not indicate a more challenging workout or increased muscle usage and noted that although wearers may be "sore because [they were]

44. *See* McCarthy, *supra* note 7, at 1A (citing comments from scientists researching toning shoes products and physical therapists considering effectiveness). R

45. *See Case #5263: Reebok International, Ltd.*, COUNCIL OF BETTER BUSINESS BUREAUS, INC., 1-2 (Dec. 13, 2010), http://www.aef.com/pdf/in_class/case_histories/nad_cases/reebok_v_nad_12-10.pdf (explaining scientific method for Reebok-funded study).

46. *See id.* (detailing researcher's process for evaluating effectiveness of toning shoes). In the Reebok-financed experiment, each of the five participants acted as her own control: because of the possibility of variables and bias, each of the participants' results with the EasyTone shoes were only compared to her other performances in the other shoes. *See id.* at 2 (describing study methodology).

47. *See id.* at 2 (reporting researcher's conclusions from studying shoe performance in controlled environment).

48. *See* Gretchen Reynolds, *Can Shoes Really Tone the Body?*, N.Y. TIMES (July 13, 2011, 12:01 AM), http://well.blogs.nytimes.com/2011/07/13/can-shoes-really-tone-the-body/ (collecting research studies about toning shoe efficacy).

49. *See* John Porcari et al., *Will Toning Shoes Really Give You a Better Body?*, AM. COUNCIL ON EXERCISE, at 2, http://www.acefitness.org/getfit/studies/toningshoes072010.pdf (last visited Jan. 24, 2012) ("There is simply no evidence to support the claims that these shoes will help wearers exercise more intensely, burn more calories or improve muscle strength and tone . . . ."); *see also About Us*, AM. COUNCIL ON EXERCISE, http://www.acefitness.org/aboutace/default.aspx (last visited Jan. 24, 2012) (explaining role and activities of ACE).

using different muscles," that fact did not "translate" into increased toning.[50]

In 2010, the National Advertising Division ("NAD") of the Better Business Bureau recommended that Reebok discontinue advertisements that claimed certain percentages of improved toning by wearing EasyTone shoes, unless the company could better substantiate those claims with more conclusive scientific evidence.[51] The investigation concluded that the 2008 Reebok-financed study did not research the product with enough individuals and did not have sufficiently conclusive results to match its advertising claims.[52] NAD was concerned that those inconclusive results could not support advertising claims that users would definitely see improved toning and/or weight loss from wearing EasyTone shoes.[53] Additionally, the reviewing panel noted in the final report that studies should reflect "real world conditions" and that the five minutes on a treadmill did not suffice to meet that requirement.[54] Reebok agreed to halt advertising of EasyTone shoes with the disputed fitness claims but disagreed with the division's interpretation regarding the flaws in the study methodology.[55]

Similarly, in December 2010, the Advertising Standards Authority ("ASA"), an independent advertising regulatory body located in the United Kingdom, determined that Reebok's advertising claims "had not been substantiated and were therefore misleading."[56] The ASA evaluated magazine and television ads sim-

50. *See* Porcari, *supra* note 49, at 2, 4 (finding no statistically significant evidence that toning shoes are more effective than normal shoes). *But see* Reynolds, *supra* note 48 (reporting that other studies financed in part by shoe companies had results indicating that toning shoes generate different forces in leg muscles or activate little-used muscles). R R

51. *See* Greg Hudson, *NAD Weighs in on Toning Shoes, FTC Announces $25 Million Settlement*, BETTER BUS. BUREAU (Sept. 29, 2011), http://www.bbb.org/blog/2011/09/nad-weighs-in-on-toning-shoes-ftc-announces-25-million-settlement-2/ (recounting NAD study from year prior). NAD is a self-regulating body that is part of the Better Business Bureau and conducts alternative dispute resolution when national advertisements are challenged. *See How NAD Works*, NAT'L ADVER. DIV., http://www.nadreview.org/AboutNAD.aspx (last visited Jan. 23, 2012) (asserting that advertisers are generally willing to abide by NAD review decisions).

52. *See* Hudson, *supra* note 51 ("[T]he researcher concluded only that test results suggested that the shoe design might potentially produce toning."). R

53. *See Case #5263: Reebok International, Ltd.*, *supra* note 45, at 4 (noting NAD concerns with Reebok's strong claims of definite results). R

54. *See id.* ("It is well-established that tests offered to support product performance claims must reflect real world conditions.").

55. *See* Hudson, *supra* note 51 (discussing resolution of NAD investigation). R

56. *See ASA Adjudication on Reebok International Ltd*, ADVER. STANDARDS AUTH. (Dec. 1, 2010), http://www.asa.org.uk/ASA-action/Adjudications/2010/12/Reebok-International-Ltd/TF_ADJ_49449.aspx (announcing regulators' decision

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ilar to the American ads (asserting percentages of improved muscle tone by using EasyTone shoes) and concluded that the small sample size of the study and the minimal duration of monitoring the muscles were insufficient to substantiate the claims.[57] Regulators concluded that because the ads were not based on "robust, scientific evidence," both the magazine and television ads would be banned unless Reebok revised the content.[58]

But advertising was not the only contested issue regarding toning shoes at that time: some doctors issued health warnings about toning shoes, especially for older consumers or those not in good health, asserting that the shoes' intended instability led to strained or inflamed Achilles tendons.[59] Other doctors expressed concerns that toning shoes would force adults to re-learn how to walk because the shoe's heel is lower than the toes and ball of the foot, which may create a problem for those with existing balance issues.[60] Consumers also reported injuries associated with use of toning shoes, including leg, hip, and joint pain, as well as tendonitis and broken bones.[61] When the Consumer Product Safety Commission (CPSC) established a user database for complaints, within two months, toning shoe consumers self-reported more injuries for those shoes than for any other product in the database and included claims of foot pain, stress fractures, torn ligaments, and broken bones in their feet.[62]

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that ads were not properly substantiated); *see also Who We Are*, ADVER. STANDARDS AUTH., http://www.asa.org.uk/About-ASA/Who-we-are.aspx (last visited Jan. 23, 2012) (explaining ASA's independent regulatory purpose in United Kingdom).

57. *See ASA Adjudication on Reebok International Ltd*, *supra* note 56 (explaining that Reebok's self-financed study was "not suitable" to substantiate advertising). R

58. *See id.* (concluding basis for decision); *see also* David Batty, *Reebok to Pay Out $25m After Shoes Fail Watchdog's No-Sweat Test*, GUARDIAN, Sept. 29, 2011, at 23, *available at* http://www.guardian.co.uk/lifeandstyle/2011/sep/28/reebok-refunds-toning-shoes-watchdog (noting that ASA decision meant that two particular Reebok ads could not air or be in magazines without "substantial revisions").

59. *See* McCarthy, *supra* note 7, at 1A (reporting on doctors' comments about possible danger of toning shoes for certain populations). R

60. *See id.* (explaining downsides of "destabilizing" effect that is intended by shoes' design).

61. *See* Don Mays, *Are Toning Shoes Unsafe? Reports of Injuries Raise Concern*, CONSUMER REPORTS (May 25, 2011, 6:00 AM), http://news.consumerreports.org/safety/2011/05/are-toning-shoes-unsafe-reports-of-injuries-raise-concern.html (listing consumer-reported injuries associated with toning shoe use); *see also* McCarthy, *supra* note 7, at 1A (providing testimonial from user who stated that she broke her ankle after one hour of using toning shoes). R

62. *See* Mays, *supra* note 61 (analyzing comments submitted to CPSC database regarding toning shoe injuries); *see also Report No. 20111006-49823-2147474610*, CONSUMER PRODS. SAFETY COMM'N (Oct. 6, 2011), http://www.saferproducts.gov/ViewIncident/1207052 (reporting foot pain and gout diagnosis); *Report No. 20110524-A3E14-2147478894*, CONSUMER PRODS. SAFETY COMM'N (May 24, 2011), R

B. The FTC Files a Complaint

In September 2011, the FTC filed a complaint in federal district court alleging that Reebok had violated Federal Trade Commission Act ("FTC Act") provisions regarding unfair and deceptive acts in commerce.[63] The complaint specified that Reebok's "advertising, marketing, and sale of purported toning footwear products" throughout the United States violated federal law.[64] The FTC argued that Reebok's representations that wearing EasyTone shoes would strengthen leg muscles and tone the lower body were unsubstantiated.[65] The FTC also included a claim that RunTone advertisements were similarly unsubstantiated with regard to the toning shoes' strengthening and toning benefits.[66] The complaint attacked both Reebok's direct and indirect implications of such benefits as a violation of the FTC Act.[67]

The Commission took particular issue with Reebok's claim of the percentage of how much an EasyTone product improved muscle tone and strength in the lower body compared to a "typical walking shoe."[68] Reebok asserted that EasyTone shoes would

http://www.saferproducts.gov/ViewIncident/1184232 (reporting three stress fractures in foot); *Report No. 20110929-DC7D0-2147474827*, CONSUMER PRODS. SAFETY COMM'N (Sept. 29, 2011), http://www.saferproducts.gov/ViewIncident/1203834 (reporting torn ligaments); *Report No.20110325-A6F3A-2147480920*, CONSUMER PRODS. SAFETY COMM'N (Mar. 25, 2011), http://www.saferproducts.gov/ViewIncident/1172786 (reporting right ankle break).

63. *See* FTC Complaint, *supra* note 13, at 1-2 (introducing basis for FTC complaint). FTC counsel filed the complaint in the Northern District of Ohio. *See id.* at 1 (identifying venue). The FTC commissioners had voted unanimously (5-0) in favor of the complaint. *See* Dina ElBoghdady, *Refunds to Run Reebok $25 Million*, WASH. POST, Sept. 28, 2011, at A13, *available at* http://www.washingtonpost.com/realestate/reebok-to-refund-25m-to-customers-who-bought-easytone-runtone-shoes/2011/09/28/gIQATmUo4K_story.html (discussing FTC complaint process and 5-0 vote). R

64. *See* FTC Complaint, *supra* note 13, at 2 (specifying violation of FTC Act and agency's jurisdiction to bring claims in district court). According to the FTC Act, "the term 'unfair or deceptive acts or practices' includes such acts or practices . . . that— (i) cause or are likely to cause reasonably foreseeable injury within the United States; or (ii) involve material conduct occurring within the United States." *See* 15 U.S.C. § 45(a) (2006) (defining unfair or deceptive acts or practices in domestic or foreign commerce). R

65. *See* FTC Complaint, *supra* note 13, at 9 (summarizing Count I). R

66. *See id.* at 10 (expressing Reebok's claims about RunTone shoes in Count III).

67. *See id.* at 9 ("Defendant has represented, directly or indirectly, expressly or by implication, that laboratory tests show that when compared to walking in a typical walking shoe, walking in EasyTone footwear will improve muscle tone and strength by 28% in the gluteus maximus, 11% in the hamstrings, and 11% in the calves.").

68. *See id.* at 4 (summarizing Reebok's percentage statistics that company included in print and video advertising).

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strengthen a wearer's butt 28 percent more and hamstring and calf muscles 11 percent more than if the wearer wore normal shoes.[69] This campaign, sometimes known as the "28-11-11" claim, appeared in print as well as in video ads broadcasted on television and over the Internet.[70] In the complaint, the FTC alleged that Reebok expressly or implicitly claimed that laboratory tests demonstrated such percentage results, but that in truth, scientific tests did not yield such results.[71]

In its request for relief, the FTC petitioned for temporary injunctive relief to stop the disputed advertising as well as a permanent ban on all of the unsubstantiated advertisements.[72] The complaint referenced how consumers had been financially harmed as a result of Reebok's ads and specified remedies to compensate these consumers who had bought EasyTone products.[73] The following day, Reebok and the FTC came to a settlement agreement, and the federal district court entered judgment on that agreement.[74] The order specified that it was for settlement purposes only and that it was not a finding that Reebok violated the FTC Act or any other federal laws, and it released Reebok from liability regarding those claims.[75]

Under the terms of the consent order, Reebok is permanently enjoined from making any claims that any toning shoe is "effective in strengthening muscles" or that such a product will lead to a specific percentage of muscle tone improvement.[76] Reebok is also prohibited from making any other representations in advertising, endorsements, or illustrations that EasyTone shoes or any other product implicated in the lawsuit have any other health or fitness

69. *See id.* at 5-7 (transcribing contents of visual and video advertisements including pertinent statistics).

70. *See id.* (collecting instances in which Reebok used claims regarding percentages of training); *see also* Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief at 22, F.C.C. v. Reebok International Ltd., 1:11-cv-02046-DCN (N.D. Ohio, Sept. 29, 2011), *available at* http://www.ftc.gov/os/caselist/1023070/110928reebokorder.pdf [hereinafter Reebok Stipulated Final Judgment] (noting official company use of term "'28-11-11' percent claims").

71. *See* FTC Complaint, *supra* note 13, at 9 (arguing that laboratory tests do not show results that Reebok asserts). R

72. *See id.* at 11 (specifying FTC request for preliminary and permanent injunctions).

73. *See id.* at 10-11 (noting consumer injury as basis for remedies).

74. *See* Reebok Stipulated Final Judgment, *supra* note 70, at 1-2 (announcing court order). R

75. *See id.* at 2 (stipulating for purposes of settlement that Reebok did not violate FTC Act).

76. *See id.* at 5 (determining main prohibition on company's advertising).

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benefits.[77] In both circumstances, however, Reebok can make health and fitness claims, and even specific percentage claims if those claims are "non-misleading and . . . [based] on competent and reliable scientific evidence."[78] If Reebok wishes to claim specifically that its toning shoes can strengthen muscles, the court order requires at least one controlled clinical study that conforms to commonly accepted scientific protocols.[79] For other health and fitness claims, Reebok must provide "relevant and reliable" evidence grounded in accepted scientific methods.[80]

The settlement stated that Reebok was liable for $25 million, which it must pay into an escrow account managed by a consulting group appointed by the FTC and used for consumer redress.[81] The FTC coordinates consumer refunds, and consumers that have also filed private class action lawsuits can be paid out of the escrow fund.[82] Reebok is also required to follow compliance reporting procedures for three years and report any changes in corporate structure to the FTC.[83] Similarly, Reebok must keep detailed records of all advertisements and promotional materials as well as any evidence they may rely on to substantiate future claims, and must record any complaints against EasyTone products for five years.[84] Following the FTC settlement, Reebok issued refund checks to 315,000 customers who had purchased EasyTone shoes and apparel.[85]

Attached to the consent order was a draft letter for Reebok to send to its retailers, notifying them of the company's decision to settle the FTC lawsuit.[86] The letter explained that Reebok has agreed to stop advertising that EasyTone shoes and the other re-

77. *See id.* at 6 (extending advertising prohibition to general health and fitness claims).

78. *See id.* at 5-6 (explaining when advertising claims are adequately substantiated).

79. *See id.* (detailing requirements for "Adequate and Well-Controlled Human Clinical Study" in order to meet substantiation guidelines).

80. *See id.* at 6-7 (defining parameters for acceptable research).

81. *See id.* at 7-8 (ordering Reebok to pay $25 million into escrow account for consumer refunds and any other equitable relief).

82. *See id.* at 8-9 (providing instructions for administration of fund).

83. *See id.* at 14-15 (listing required compliance monitoring documents).

84. *See id.* at 16-17 (recounting Reebok's recordkeeping requirements for five years).

85. *See Refunds Stemming From Reebok's Settlement With FTC Mailed to Consumers Who Bought EasyTone and RunTone Shoes and EasyTone Apparel*, FED. TRADE COMM'N (Aug. 7, 2012), http://www.ftc.gov/opa/2012/08/reebok.shtm (updating refund information).

86. *See* Reebok Stipulated Final Judgment, *supra* note 70, at 22 (including template for Reebok retailers). R

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lated products "increase or improve muscle tone, muscle strength, or muscle activation . . . or improve posture."[87] The letter specifically noted that the "28-11-11" percent of toning improvement is now a prohibited advertisement.[88] In the attachment, Reebok's president instructed shoe retailers to remove posters and shoebox inserts that contain the disputed claims and to cover up claims on shoeboxes or clothing tags.[89]

In the press conference announcing the settlement, David Vladeck, director of the FTC's Bureau of Consumer Protection ("BCP"), stated that a goal of the action was to make "national advertisers [ ] understand that they must exercise some responsibility and ensure that their claims for fitness gear are supported by sound science."[90] However, FTC personnel would not comment on whether they were investigating any other toning shoe manufacturers for similar concerns.[91] In response to the settlement, a Reebok spokesman stated that the company did not agree with the FTC's conclusions but decided to settle nevertheless.[92] The spokesman added that the company still supports its "EasyTone technology and plans to develop and sell EasyTone products but with a different marketing strategy."[93]

87. *See id.* (summarizing settlement details).

88. *See id.* (specifying percentage claims as target of settlement).

89. *See id.* (recommending changes for retailers).

90. *See Reebok to Pay $25 Million in Customer Refunds To Settle FTC Charges of Deceptive Advertising of EasyTone and RunTone Shoes*, *supra* note 20 (quoting BCP director at press conference). **R**

91. *See* Zmuda I, *supra* note 1 (noting that FTC BCP director declined to answer whether agency was considering companies that made similar claims as Reebok); *see also Lawsuit Claims Dozens Injured by Company's Special Shoes*, SCRIPPS MEDIA (Jan. 18, 2012), http://www.kjrh.com/dpp/news/national/lawsuit-claims-dozens-injured-by-companys-special-shoes (reporting that class action lawsuit has been filed against Skechers based on injuries allegedly caused by toning shoes; this lawsuit is largest class action filed against Skechers). In May 2012, the FTC announced that it had reached a $40 million settlement with Skechers regarding unsubstantiated advertising for toning shoes. *See* Jim Puzzanghera, *Skechers to Settle Toning Shoe Cases*, L.A. TIMES, May 17, 2012, at B1, http://articles.latimes.com/2012/may/16/business/la-fi-mo-skechers-settlement-defense-20120516 (reporting that Skechers settled case with FTC to avoid costs and time associated with litigation). **R**

92. *See* Martin & O'Connor, *supra* note 5, at B1 (referencing official Reebok response to settlement). **R**

93. *See id.* (reporting on company's commitment to EasyTone products); *see also* Suzanne Vranica, *Thumbs Up for Mini Vader: Best and Worst Ads of 2011*, WALL ST. J., Dec. 27, 2011, at B1, http://online.wsj.com/article/SB10001424052970204058404577108861568521248.html (noting Reebok comment that company planned to continue selling EasyTone shoes).

IV. NO SWEAT: HOW THE FTC REVIEWS DECEPTIVE ADVERTISING IN WEIGHT LOSS CLAIMS

Gimmicky claims have become customary in advertising for weight loss products, and some fitness products are so inane that it is hard to imagine widespread consumer fraud.[94] The balance, however, lies in determining whether consumers themselves should be responsible for investigating more credible weight loss products, or if the federal government, specifically the FTC, should step in due to an overriding concern for consumer health and safety.[95] Advertisers, journalists, government officials, and consumers constantly grapple over whether the maxim of *caveat emptor*, or "let the buyer beware," is economically healthy or dangerous to consumers.[96] This dispute is even more contentious when large, reputable retailers market products claiming scientific health and weight loss benefits because their expansive consumer bases could lead to widespread and substantial harm from improper advertising.[97]

A. Basis for FTC Authority

The FTC is the government agency responsible for ensuring fair business practices and effective competition in the marketplace.[98] The Commission's BCP exists "to protect consumers

94. *See* Hadley Freeman, *Reebok EasyTone: The Shoe That Undermines All Fitness Advertising*, GUARDIAN (Sept. 29, 2011, 15.57 EDT), http://www.guardian.co.uk/lifeandstyle/blog/2011/sep/29/reebok-easytone-ftc-fine (presenting list of odd fitness products and linking to video ads); *see also Has Reebok Misled With its EasyTone Ads? No 'Butts' About It*, WHARTON SCHOOL OF U. PA. (Sept. 30, 2011), http://knowledgetoday.wharton.upenn.edu/2011/09/has-reebok-misled-with-its-easytone-ads-no-butts-about-it/ ("Certainly, companies make outsized claims all of the time – just think of any cosmetic product that promises to lift sagging skin or defy aging. Sometimes, those claims are fuzzy and imply an outcome rather than promising concrete results based on science.").

95. *See generally* Marla Pleyte, *Online Undercover Marketing: A Reminder of the FTC's Unique Position to Combat Deceptive Practices*, 6 U.C. DAVIS BUS. L.J. 14 (2006) (discussing why consumers cannot be expected to make informed decisions and thus, why government action is needed).

96. *See* Bruce Weinstein, *Let's Abolish* Caveat Emptor, BUSINESS WEEK (Apr. 16, 2010, 4:21PM EST), http://www.businessweek.com/managing/content/apr2010/ca2010048_989105.htm (arguing that consumers need greater protection from false and deceptive advertising and asserting that advertisers who voluntarily undertake that responsibility will be helped as well).

97. *See* Richard S. Higgins & Fred S. McChesney, *Materiality, Settlements, and the FTC's Ad Substantiation Program: Why Wonder Bread Lost No Dough*, 32 MANAGERIAL & DECISION ECON. 71, 81 (2011) (citations omitted) ("Almost all FTC advertising cases are brought against non-descript, penny-ante firms; national advertisers are big – and newsworthy – fish . . . As one industry source put it, 'big brands make big targets.' And bigger fish can be more valuable to bureaucratic fishers.").

98. *See About the Federal Trade Commission*, FED. TRADE COMM'N, http://www.ftc.gov/ftc/about.shtm (last visited Jan. 26, 2012) (explaining role of FTC in

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against unfair, deceptive, or fraudulent practices in the marketplace."[99] The BCP is responsible for collecting consumer complaints about possible fraudulent products, initiating investigations, and enforcing FTC laws and regulations regarding advertising.[100] This power to curb unsubstantiated advertising stems from the Federal Trade Commission Act's "Section 5 powers," which comprise part of the Commission's larger authority to prohibit advertisements that are likely to deceive customers.[101] The FTC is generally authorized to prevent persons and corporations from engaging in "unfair methods of competition . . . and unfair or deceptive acts or practices" related to commercial ventures.[102] Along with substantiation of advertisements, the Commission also evaluates direct and implied representations or omissions in ads that could potentially mislead consumers.[103]

The FTC has statutory authority to promulgate regulations interpreting the FTC Act's prohibition on unfair and deceptive advertising pursuant to the Administrative Procedure Act's ("APA") guidelines for agency rulemaking.[104] In regard to individual disputes about specific advertisements, the Commission has a variety of tools at its disposal to enforce statutory and regulatory schemes.[105] The agency can internally investigate allegedly false or deceptive advertising by filing a complaint against the advertiser and requiring the advertiser to defend its claim at an administrative

protecting marketplace). The FTC is responsible, among other roles, for evaluating companies' mergers and acquisitions to ensure that there are no anticompetitive business practices that could harm consumers on a large scale. *See Welcome to the Bureau of Competition*, FED. TRADE COMM'N, http://www.ftc.gov/bc/index.shtml (last visited Feb. 11, 2012) (explaining major function of FTC regulatory authority).

99. *See About the Bureau of Consumer Protection*, FED. TRADE COMM'N, http://www.ftc.gov/bcp/about.shtm (last visited Jan. 21, 2012) (presenting BCP's mission statement and summarizing major goals).

100. *See id.* (outlining BCP's seven divisions).

101. *See* 15 U.S.C. § 45 (a) (2006) (providing general scope of FTC authority in unfair trade practices); *see also* FTC PRACTICE AND PROCEDURE MANUAL, 2007 A.B.A. SEC. ANTITRUST L. 22 (designating code provision as Section 5 of FTC Act).

102. *See* § 45(a) (stating FTC Act powers).

103. *See* FTC PRACTICE AND PROCEDURE MANUAL, *supra* note 101, at 23-24 (summarizing FTC authority with regard to other advertising enforcement). R

104. *See* 15 U.S.C. § 57(a) (2006) (establishing FTC authority to interpret statutory provisions on false and deceptive advertising); *see also* 5 U.S.C. § 553 (2006) (presenting rulemaking procedures in APA).

105. *See generally* § 45 (listing options that FTC can employ to prohibit unfair and deceptive advertising).

hearing.[106] Final decisions handed down by the FTC through this process are reviewable by federal courts.[107]

Additionally, the FTC Act provides the Commission with the authority to enforce advertising laws through direct action in federal district court.[108] Section 12 of the FTC Act allows for the agency to bring suit in federal court when it "has reason to believe . . . that any person, partnership, or corporation is engaged in, or is about to engage in, the dissemination or the causing of the dissemination of any advertisement" whose falsity is likely to encourage consumers to purchase "food, drugs, devices, services, or cosmetics."[109] Under this provision, the Commission can seek a temporary restraining order or preliminary injunction to stop the dissemination of the disputed advertisement.[110] This section also provides that the district court can later order a permanent injunction if the government has provided the requisite proof.[111]

B. FTC Enforcement of Unsubstantiated Weight Loss Claims

In 1972, the FTC established the controlling legal requirement regarding advertising substantiation: an advertiser making an "affirmative product claim" must have a "reasonable basis" for that claim.[112] This standard entails a fact-sensitive inquiry dependent

106. *See* § 45(b)-(c) (outlining FTC internal processes for bringing complaint against advertiser and conducting administrative hearing).

107. *See* § 45(g)-(j) (referencing roles of Supreme Court and federal appellate courts in reviewing and setting aside Commission's final orders against advertisers).

108. *See* 15 U.S.C. § 53 (2006) (providing procedure for enforcing FTC Act in federal court system). Consumers can also seek enforcement of advertising laws outside the FTC's enforcement powers by bringing personal lawsuits under the Lanham Act. *See* 15 U.S.C. § 1125(a) (2006) (creating right of action for "any person who believes that he or she is or is likely to be damaged by" particular "false or misleading" advertisement); *see also* KENNETH A. PLEVAN & MIRIAM L. SIROKY, ADVER. COMPLIANCE HANDBOOK 3 (2d ed. 1991) (referencing this provision of United States Code as part of Lanham Act).

109. *See* § 53(a) (permitting FTC to bring civil suit for suspected violation of §52(a)); § 52(a) (prohibiting dissemination of false advertisements related to "inducing" customers to purchase certain products); *see also* FTC Complaint, *supra* note 13, at 2 (identifying 15 U.S.C. § 52 as codified version of Section 12 of FTC Act). R

110. *See* § 53(b) (noting requirements that must be proven before district court will issue injunction on advertisement).

111. *See id.* ("That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction.").

112. *See* In re Pfizer Inc., 81 F.T.C. 23, 30 (1972) (stating requirement for advertisers to possess "reasonable basis" for claims).

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on the facts available in each case.[113] Relevant considerations involve "the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable."[114] Existence of substantiation is material to consumers because consumers consider the basis of a claim important in their decision to purchase a product.[115] Consequently, it is undisputed that unsubstantiated advertisements "are deceptive as a matter of law" because the law states that unsubstantiated advertisements have no reasonable basis for the claims they assert.[116]

In addition, the FTC has stated that when an advertiser makes an express claim, such as "tests prove" or "studies show," it expects the advertiser to possess at least that level of substantiation (actual tests or studies demonstrating the claimed result) to avoid a violation of the FTC Act.[117] The Commission has also established specific heightened requirements for substantiation of claims that reference a product's effectiveness with regard to health and safety.[118] Such claims must be supported by "reliable and competent scientific evidence."[119]

However, despite these legal sources of authority, the FTC has not promulgated any formal regulations regarding advertisers' spe-

113. *See id.* ("This standard is determined by the circumstances at the time the claim was made, and further depends on both those facts known to the advertiser, and those which a reasonable prudent advertiser should have discovered.").

114. *See FTC Policy Statement*, *supra* note 19 (listing possible factors that could be important to reasonable basis determination); *see also Pfizer Inc.*, 81 F.T.C. at 30 (considering "consumer reliance" on claims as element of inquiry regarding whether claim is adequately substantiated). R

115. *See FTC Policy Statement*, *supra* note 19 (holding that advertisers' "reasonable basis" for claims is material to consumers). R

116. *See* F.T.C. v. Direct Mktg. Concepts, Inc., 624 F.3d 1, 8 (1st Cir. 2010) (stating settled law regarding unlawfulness of unsubstantiated advertisements); *see also FTC Policy Statement*, *supra* note 19 ("[A] firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act."). R

117. *See FTC Policy Statement*, *supra* note 19 (specifying level of substantiation for express claims compared to implied claims). R

118. *See* Randal Shaheen & Amy Ralph Mudge, *Has the FTC Changed the Game on Advertising Substantiation?*, 25 A.B.A. SEC. ANTITRUST 65, 66 (2010), *available at* http://www.americanbar.org/content/dam/aba/publishing/antitrust_source/Fall10_ShaheenC.authcheckdam.pdf (noting special requirements for health and safety claims); FTC PRACTICE AND PROCEDURE MANUAL, *supra* note 101 (noting health and safety claims as demanding higher level of substantiation). R

119. *See* Novartis Corp. et al., 127 F.T.C. 580, 580 (1999) (establishing standard of "competent and reliable scientific evidence" in pharmaceutical case); *see also* Shaheen & Mudge, *supra* note 118, at 66 (indicating *Novartis Corp.* language as enduring standard for general substantiation of health and safety claims). R

cific responsibilities to substantiate health claims pursuant to "reasonable basis" and "reliable and competent scientific evidence."[120] The agency has explicitly declined on several occasions to implement such requirements that define reliable and competent scientific evidence in the substantiation context.[121] The FTC's minimal official guidance supports a wide range of acceptable methods that an advertiser can use to substantiate claims:

> "*Competent and reliable scientific evidence*" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.[122]

As a result, substantiation is only evaluated on a case-by-case basis in which the FTC targets individual advertisers for violation of general substantiation policies and negotiates settlements.[123] These settlements are expressed in consent orders that are entered into at the

120. *See* Shaheen & Mudge, *supra* note 118, at 66 (stating that FTC has refused to adopt bright-line procedures for substantiation like that of Food and Drug Administration (FDA) for new drug applications). Over the last several decades, however, the FTC has occasionally flirted with the idea of promulgating strict testing guidelines to ensure claims are scientifically substantiated. *See id.* (referencing Commission's reason for considering stricter standards). In 1983, the agency published in the Federal Register a request for public comment about how to improve substantiation rules, including asking advertisers whether they would prefer "general standards" (merely a "reasonable basis" for a claim) or "specific standards" about amount and documentation of substantiation; *see also* Advertising Substantiation Program; Request for Comments, 48 Fed. Reg. 10,471, 10,472-10,473 (Mar. 11, 1983) (presenting various options for substantiation guidance). In response to comments received, the FTC subsequently published the *FTC Policy Statement Regarding Advertising Substantiation*, which did not authorize formal requirements but remains the current guiding document about substantiation. *See FTC Policy Statement*, *supra* note 19 (announcing statement as in response to request for comments); *see also* Shaheen & Mudge, *supra* note 118, at 65 (referencing FTC Policy as "memorializing" Commission's position on advertising substantiation). **R** **R** **R**

121. *See, e.g.*, Diet Center et al., 5 Trade Reg. Rep. (CCH) ¶23,357 (1993) (providing FTC letter denying advertisers' petition that Commission promulgate official rules for substantiation of weight loss advertisements); *Advertising Claims for Dietary Supplements: Denial for Petition of Rulemaking*, *supra* note 19 (denying advertisers' request to promulgate rule defining "competent and reliable scientific evidence" or alternatively, to issue advisory opinions to individual advertisers concerned about adequate substantiation). **R**

122. *See Novartis Corp.*, 127 F.T.C. at 725 (defining "competent and reliable scientific evidence"); *see also* Shaheen & Mudge, *supra* note 118, at 66 (analyzing *Novartis Corp.* language to encourage FTC flexibility in accepting substantiation evidence). **R**

123. *See Diet Center*, 5 Trade Reg. Rep (CCH), at ¶23,357 ("Bringing individual cases permits the Commission to adjust the forum for relief, and the remedy

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district court level, and include injunctions on the publishing of unsubstantiated advertisements, as well as terms regarding the advertiser's monetary penalty and obligations to comply with future FTC monitoring.[124] The results of advertiser-specific consent orders are only binding on the defendant advertiser, however, and have minimal precedential value for other advertisers making similar unsubstantiated claims.[125]

C. FTC Crackdown on Weight Loss Advertising

In 1997, the FTC publicized its comprehensive scheme to crack down on false and deceptive weight loss advertising, which was dubbed Operation Waistline.[126] The Commission announced seven consent orders on the same day, all of which imposed restrictions and penalties on advertisers of weight loss products including diet programs, skin patches, and shoe insoles.[127] The total consumer redress ordered by those seven settlements totaled over $700,000.[128] Defined as a "coordinated, long-term consumer education and law enforcement program," Operation Waistline sought to serve the dual goals of enforcing advertising laws and encouraging consumers to avoid purchasing deceptively advertised products.[129] Along with the consent orders, the FTC reviewed over 100 additional weight loss advertisements and recommended that the

sought, to the facts of each case, while remaining consistent with appropriate precedent.").

124. *See, e.g.*, Reebok Stipulated Final Judgment, *supra* note 70 (noting various restrictions on advertiser's ability to promote its unsubstantiated products). R

125. *See* Angela Saad, *Challenging Binding Arbitration: A New Use for the FTC*, 10 J. CONSUMER & COMMERCIAL L. 130, 132 (2007) (discussing limitations of consent orders as precedent in future contract actions); *see also* Lesley Fair, *The Reebok Settlement: What the FTC Order Means for Advertisers and Retailers*, FED. TRADE COMM'N (Sept. 29, 2011), http://business.ftc.gov/blog/2011/09/reebok-settlement-what-ftc-order-means-advertisers-and-retailers [hereinafter Fair I] ("Of course, the terms of the lawsuit apply only to Reebok, but experienced advertisers understand the benefits of mining FTC orders for compliance nuggets applicable to their business.").

126. *See FTC Announces "Operation Waistline" – A Law Enforcement and Consumer Education Effort to Stop Misleading Weight Loss Claims*, FED. TRADE COMM'N (last visited Feb. 27, 2012), http://www.ftc.gov/opa/1997/03/waistlin.shtm [hereinafter *FTC Announces "Operation Waistline"*] (introducing weight loss advertising enforcement program).

127. *See id.* (listing types of products targeted by FTC investigation).

128. *See id.* (stating amount of money that advertisers in violation of law were required to pay to government to be used for consumer redress).

129. *See id.* (summarizing overall goals of enforcement effort).

publishers of the advertisements improve self-regulation practices to encourage compliance with the law.[130]

Two of the Operation Waistline consent orders applied sanctions to shoe insole manufacturers, who claimed that their products induced "weight loss by stimulating certain areas of the feet."[131] The FTC brought a complaint against Guildwood Direct Limited alleging that the company's "Slimming Insoles" product did not have adequate substantiation for claims that the product caused rapid and drastic weight loss.[132] Guildwood had disseminated print advertisements claiming that it had conducted tests to prove the effectiveness of the Slimming Insoles, and that a high percentage of the test subjects had lost weight using the product.[133] In the consent order, the Commission prohibited Guildwood from making any representations that the Slimming Insoles were effective in causing weight loss or facilitating fat burning (regardless of change in diet or exercise) unless the company had competent and reliable scientific evidence.[134] The FTC defined competent and reliable evidence as studies conducted in light of existing and reliable scientific parameters and expertise, similar to the *Novartis Corp.* language.[135] As a penalty, the FTC required the company to pay $40,000 into an escrow fund that the government would return to Slimming Insoles purchasers.[136]

Similarly, the FTC filed a complaint against BodyWell, Inc. for advertising weight loss benefits of its "Slimming Soles" insoles without substantiating those claims.[137] BodyWell had disseminated ads claiming that users of the products could wear the insoles for six weeks and lose sixteen pounds without changes in diet or exer-

130. *See id.* (noting additional steps taken by Commission for Operation Waistline).

131. *See The Federal Trade Commission Today Announced the Following Actions*, FED. TRADE COMM'N (June 20, 1997), http://www.ftc.gov/opa/1997/06/petapp34.shtm (detailing consent orders against shoe insole retailers).

132. *See* Guildwood Direct Ltd., 123 F.T.C. 1558, 1562 (1997) (providing basis for Commission's charge against company).

133. *See id.* at 1559-61 (showing that product was allegedly developed by doctor and that tests had yielded favorable results; i.e. that "58% of the individuals tested lost 14 lbs. or more. . . 27% of the individuals tested lost 10 lbs. to 14 lbs. . . 15% of the individuals tested lost up to 10 lbs.").

134. *See id.* at 1571-72 (listing terms of prohibitions in court order).

135. *See id.* at 1570 (defining terms applicable to order). For a more detailed discussion of the Commission's development of substantiation guidelines, see *supra* notes 112-125 and accompanying text. R

136. *See Guildwood*, 123 F.T.C. at 1573 (requiring company to pay specified amount in consumer redress).

137. *See* BodyWell, Inc., 123 F.T.C. 1577, 1581 (1997) (specifying focus of complaint).

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cise.[138] The FTC asserted that the "scientific studies" that BodyWell had relied upon to substantiate the ads did not show the advertised results, especially within the six-week timeframe for success that the company advertised.[139] In the subsequent consent order, the FTC fined BodyWell $100,000 in consumer redress.[140] The order also mandated that the company could no longer claim that Slimming Soles helped users lose weight or burn fat in any specified timeframe unless it had competent and reliable scientific evidence to substantiate those claims.[141]

D. Efforts to Clarify Substantiation Doctrine for Health Claims

In recent years, the FTC has slowly been clarifying its expectations about substantiating health and safety claims through consent decrees imposed on individual advertisers.[142] David Vladeck, the director of the BCP, stated in a 2009 speech that FTC investigators would use more precise language in consent decrees so that defendants, courts, and future advertisers could have a picture of what scientific evidence is necessary to substantiate a claim.[143] The FTC has fulfilled this expectation by providing detailed language in more recent consent orders about what types of evidence advertisers need before they can disseminate ads again without being in violation of the order.[144] However, some commentators have suggested that through this process, the Commission has informally instituted a new standard for all advertisers' substantiation.[145] For

138. *See id.* at 1578-81 (outlining BodyWell's advertising methods for Slimming Soles).

139. *See id.* at 1582 (challenging content of representations as well as defined time in which results would appear).

140. *See id.* at 1592 (mandating consumer redress payment of $100,000).

141. *See id.* at 1590-91 (ordering cessation of unsubstantiated advertisements). As in *Guildwood*, competent and reliable scientific evidence in *BodyWell* was defined as the FTC required in the 1972 Policy Statement. *See id.* at 1590 (defining competent and reliable scientific evidence).

142. *See* Jennifer Grebow, *Case History: Lane Labs and the FTC*, NUTRITIONAL OUTLOOK (Feb. 8, 2012), http://www.nutritionaloutlook.com/article/case-history-lane-labs-and-ftc-3-8982 (evaluating consent orders that use precise language to issue injunctions).

143. *See* David C. Vladeck, Dir. FTC Bureau of Consumer Protection, Priorities for Dietary Supplement Advertising Enforcement 11 (Oct. 22, 2009), *available at* http://www.ftc.gov/speeches/vladeck/091022vladeckcrnspeech.pdf ("We will be looking for more precise injunctive language in future orders that will provide clearer guidance to defendants and courts alike as to the amount and type of scientific evidence that will be required in future advertising.").

144. *See* Shaheen & Mudge, *supra* note 118, at 66-67 (suggesting that FTC has recently provided greater specificity in consent orders). **R**

145. *See* Grebow, *supra* note 142 (quoting lawyers that analyzed recent FTC consent orders). **R**

example, in the most recent consent orders regarding health and safety claims, in each case the FTC has required that advertisers provide two placebo-controlled, randomized studies tested on humans to substantiate advertisements.[146]

In 2010, in *F.T.C. v. Iovate Health Sciences USA, Inc.*,[147] the FTC settled a suit against dietary supplement manufacturer Iovate Health Sciences regarding the company's representations about the supplements' ability to aid in weight loss in addition to other claims.[148] For claims that Iovate's products induce either weight loss or "rapid" weight loss, the Commission required the company to substantiate claims with "two adequate and well-controlled human clinical studies" done by independent scientists and evaluated with respect to other available data.[149] The settlement order also prohibited Iovate from making any other health or efficacy claims about its dietary supplements unless those claims were substantiated by tests conducted in accordance with generally recognized scientific principles and whose results were compared to other available data.[150] The FTC, however, specifically exempted from this substantiation requirement any "claims regarding bodybuilding and exercise performance (e.g., increased muscle mass or body mass, increased strength and power, improved weight training performance, increased work-out intensity, improved muscle endurance, or improved muscle recovery)."[151]

Similarly, in *In re Nestlé Healthcare Nutrition, Inc.*,[152] the FTC and the Nestlé corporation entered into a consent order in 2011 regarding the substantiation of advertisements for children's nutritional drinks.[153] The Commission claimed in its complaint that Nestlé's advertisements for its "BOOST Kid Essentials" did not have ade-

146. *See id.* (noting similarity in consent orders resolving recent substantiation disputes).

147. Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief, F.T.C. v. Iovate Health Sciences USA, Inc., Case No. 10-CY-587 (W.D.N.Y. July 29, 2010), *available at* http://www.ftc.gov/os/caselist/0723187/100729iovatestip.pdf [hereinafter Iovate Stipulated Judgment].

148. *See id.* at 4-9 (listing all types of claims that FTC determined required more reliable substantiation).

149. *See id.* at 6-7 (specifying substantiation requirements for weight loss claims). The order also requires that Iovate comply with all FDA regulations regarding labeling and promotion of over-the-counter dietary supplement products. *See id.* at 6 (referencing claims that require FDA approval).

150. *See id.* at 7-8 (providing standard for substantiation for any other claim not involving weight loss).

151. *See id.* at 8 (excusing muscle tone claims from requirement for substantiation).

152. 151 F.T.C. 1 (2011).

153. *See id.* at 5-12 (stating terms of consent order).

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quate substantiation for the claims that the drinks improve children's immune systems and help children avoid respiratory illnesses.[154] The FTC also took issue with Nestlé's claims that if children drank the product, they would have fewer absences from school or daycare programs, and would have a decreased risk of suffering from diarrhea.[155]

In the Nestlé consent order, the FTC determined that different types of claims required differing levels of substantiation depending on the type of claim being made.[156] For claims that BOOST drinks help children avoid acute diarrhea, and limit the number of absences from school or daycare, the FTC required "two adequate and well-controlled human clinical studies of the product, or of an essentially equivalent product," as investigated by two separate researchers.[157] The order also noted that the results of the studies need to be evaluated "in light of the entire body of relevant and reliable scientific evidence."[158] In contrast, the next section of the consent order required that Nestlé substantiate any other claims about the "health benefits, performance, or efficacy" of the products through the more general standard of tests, analyses, research, studies, or other evidence that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results."[159]

V. KICKING TONING SHOE BUTT: THE FTC'S NEED TO CREATE OFFICIAL GUIDANCE REGARDING SUBSTANTIATION OF FITNESS CLAIMS

The FTC can better protect consumers by flexing its governmental muscle and creating legally binding standards to which fit-

154. *See id.* at 2-4 (asserting specifics of Nestlé advertising with dubious substantiation).

155. *See id.* (listing additional claims about efficacy of BOOST drinks that Commission argued were unsubstantiated).

156. *See id.* at 6-7 (separating claims for avoiding diarrhea versus claims about other health benefits or efficacy). Additionally, the consent order required Nestlé's advertisements to adhere to labeling requirements as stipulated by the FDA. *See id.* at 7 (mandating compliance with regulations promulgated by FDA through authority granted in Nutrition Labeling and Education Act).

157. *See id.* at 7 (detailing standards of clinical testing to substantiate claims).

158. *See id.* (requiring that study results used to substantiate advertisements be in conformity with other test results).

159. *See id.* (stating recommendations for less specific claims about BOOST drink advantages).

ness advertisers must abide.[160] By establishing such fitness standards, the Commission would assert greater regulatory legitimacy, as individual consent orders requiring substantiation would have the support of detailed published guidance.[161] This is contrary to current methods, in which the FTC issues individual consent orders without reference to precedent or reasoning other than the statutory basis of its authority.[162] Based on the FTC's prior regulation of products that claim to help with weight loss and improve athletic performance, these fitness substantiation standards should apply to all "fitness products," including athletic shoes, apparel, and exercise equipment such as exercise machines or smaller workout tools.[163]

Additionally, such guidance would be a useful resource for advertisers that desire to comply with the law and avoid FTC Act violations.[164] This is especially pertinent given that some advertisers in the past have requested guidance about substantiation and have received none.[165] Fitness advertisers, especially following the Reebok fallout, are likely to be more cautious in their advertising claims and may well desire greater government guidance about how to substantiate their claims.[166]

160. *See* Pleyte, *supra* note 95 (asserting that FTC has "arsenal of tools at its disposal" to protect consumers from deceptive online advertising but declines to do so). **R**

161. *See id.* (suggesting role of FTC as predominant source to protect consumers from online scams and deceptive advertising, instead of consumers using private remedies or existing regulations).

162. For a more detailed discussion of how the FTC currently enforces advertising laws through consent orders, see *supra* notes 124-125 and accompanying text. **R**

163. *See How's That Work-Out Working Out? Tips on Buying Fitness Gear*, FED. TRADE COMM'N, http://www.ftc.gov/bcp/edu/pubs/consumer/alerts/alt113.shtm (last visited Mar. 17, 2012) (listing types of workout products that consumers should evaluate closely before purchasing); *Pump Fiction*, FED. TRADE COMM'N (Nov. 2003), http://www.ftc.gov/bcp/edu/pubs/consumer/products/pro10.pdf (stating importance of carefully considering weight and cardio exercise machines).

164. *See FTC Publishes Final Guides Governing Endorsements, Testimonials*, FED. TRADE COMM'N (Oct. 5, 2009), http://www.ftc.gov/opa/2009/10/endortest.shtm ("The Guides are administrative interpretations of the law intended to help advertisers comply with the Federal Trade Commission Act; they are not binding law themselves.").

165. *See, e.g.*, *Advertising Claims for Dietary Supplements: Denial for Petition of Rulemaking*, *supra* note 19 (arguing that Commission should provide more detailed instructions about how to substantiate advertisements). **R**

166. *See* Katy Bachman, *Reebok's $25M Settlement Signals New Day at FTC*, ADWEEK (Sept. 29, 2011), http://www.adweek.com/news/advertising-branding/reeboks-25m-settlement-signals-new-day-ftc-135320 (interviewing attorneys that suggest that Reebok decision has ramifications for advertisers because of deterrence effect).

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This section will discuss the reasons why the FTC needs to create official guidelines for substantiating fitness advertisements for the benefit of consumers and advertisers alike. Section A will discuss the Commission's overriding need to protect consumers, as well as consumers' inability to determine whether claims have been properly substantiated.[167] Section B will discuss the FTC's historic interest in ensuring safe fitness products and how the Reebok decision starts a new era of this protection.[168] Section C will evaluate the current lack of guidance and the FTC's flexible view of fitness substantiation.[169] Section D will consider why current FTC publications are insufficient to guide fitness advertisers.[170]

A. Need to Protect Consumers from Unsubstantiated Fitness Advertising

In *In re Pfizer Inc.*,[171] the leading standard for substantiation of claims in advertising, the FTC emphasized the importance of ensuring government regulation of proper substantiation: "The consumer simply cannot make the necessary tests or investigations to determine whether the direct and affirmative claims made for a product are true."[172] As part of its regulatory authority, the FTC provides consumer education materials to warn consumers away from scams and help them make informed decisions about purchasing goods and services.[173] For example, with regard to health and fitness claims, the Commission's website hosts a number of consumer protection initiatives, including "fact sheets" that contain tips on buying fitness gear and things to beware, as well as the "Red Flag" campaign, which is an entire site dedicated to helping con-

167. For a more detailed discussion about the relationship between consumers and unsubstantiated advertisements, see *infra* notes 171-187 and accompanying text. R

168. For a more detailed discussion about how the FTC has regulated fitness products in the past decades, see *infra* notes 188-198 and accompanying text. R

169. For a more detailed discussion about how fitness product substantiation is flexible, see *infra* notes 199-218 and accompanying text. R

170. For a more detailed discussion about the inapplicability of existing substantiation guidance, see *infra* notes 219-232 and accompanying text. R

171. 81 F.T.C. 23 (1972).

172. *See id.* at 28 (concluding that consumers' limited resources make it impossible for them to educate themselves sufficiently about advertisers' claims).

173. *See Consumer Information*, FED. TRADE COMM'N, http://www.ftc.gov/bcp/consumer.shtm (last visited Mar. 17, 2012) (listing categories where FTC has published documents about specific scams and overall tips for consumers).

sumers identify false claims through examples of improper advertisements.[174]

However, FTC consumer education resources are insufficient within the current enforcement system to help consumers determine whether advertisements for fitness products are unsubstantiated.[175] Much of this concern stems from the fact that consumers are generally unfamiliar with the scientific bases for substantiation, and FTC consumer materials cannot adequately help consumers determine if advertisements are supported by reliable scientific research.[176] Unlike consumer testimonials or celebrity endorsements, in which a potential buyer can weigh the credibility of the endorser, a consumer is less likely to have the resources or knowledge to evaluate the reliability of a scientific study.[177]

Additionally, the pervasiveness of online advertising for weight loss merchandise, including fitness products, suggests that the FTC should create more specific substantiation guidelines.[178] Advertisers have more ability than ever to access consumers through online

174. *See Pump Fiction*, *supra* note 163 (recommending what consumers should consider before purchasing fitness equipment); *Weighing the Evidence in Diet Ads*, FED. TRADE COMM'N (Nov. 2004), http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea03.pdf (listing possibly suspicious weight loss claims that consumers should be wary of); *see also What You Can Do*, FED. TRADE COMM'N, http://www.ftc.gov/bcp/edu/microsites/redflag/whatyoucando.html (last visited Mar. 9, 2012) (presenting "Red Flag" FTC website as specific consumer resources to spot and protect against false claims). **R**

175. *See generally* Lydia B. Parnes & Carol J. Jennings, *Through the Looking Glass: A Perspective on Regulatory Reform at the Federal Trade Commission*, 49 ADMIN. L. REV. 989, 1004-05 (1997) (considering role of consumer education along with regulatory enforcement); Svetlana Milina, Note, *Let the Market Do Its Job: Advocating an Integrated Laissez-Faire Approach to Online Profiling Regulation*, 21 CARDOZO ARTS & ENT. L.J. 257, 281-83 (2003) (evaluating relationship of consumer education to FTC law enforcement tactics).

176. *See generally* Lesley Fair, *Weighing the Evidence: Substantiating Claims for Weight Loss Products*, FED. TRADE COMM'N, http://business.ftc.gov/documents/weighing-evidence-substantiating-claims-weight-loss-products (last visited Mar. 17, 2012) [hereinafter Fair II] (stating that consumers should be wary of claims not supported by "clinical research [that] must meet the rigorous standards for accuracy generally accepted by experts in the field"). *But see How's That Work-Out Working Out? Tips on Buying Fitness Gear*, *supra* note 163 (suggesting that consumers should be alert for substantiation discrepancies when ads claim that exercise products cause "spot reduction" weight loss). **R**

177. *See* Consuelo Lauda Kertz & Roobina Ohanian, *Source Credibility, Legal Liability, and the Law of Endorsements*, 11 J. PUB. POLICY & MKTG. 12, 12 (1992) (considering how audiences view celebrity and consumer endorsements); *see also* 16 C.F.R. § 255.2 (2009) (citing FTC guidelines regarding consumer endorsements in advertisements).

178. *See generally* Daniel H. Pink, *America's Top Cybercop*, FAST CO., Dec. 19, 2007, at 38, *available at* http://www.fastcompany.com/magazine/39/topcybercop.html?page=0%2C3 (discussing how advertisers can take advantage of Internet mechanisms to access and dupe consumers).

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media by sharing their messages about products through their own websites and encouraging consumers to spread the word through social networking.[179] This tendency is exemplified by the FTC identifying in its complaint against Reebok that the company had disseminated photo and video advertisements on its own website as well as through the social networks Facebook and Twitter and video hosting site YouTube.[180] The Commission has demonstrated in previous lawsuits and campaigns that it takes truthful online advertising seriously, which indicates that substantiation of online ads should be important for the FTC to consider or address.[181]

The FTC should also take a more proactive approach in establishing such substantiation guidelines because it is increasingly apparent that consumers have little individual authority to protect themselves from unsubstantiated claims.[182] Even if informed consumers believe that they have purchased products based on an unsubstantiated advertisement, current legal doctrine may preclude them from obtaining relief.[183] In the past several years, some courts have indicated that the FTC retains sole power in curbing unsubstantiated advertising and that consumers must obtain relief through administrative means.[184] This situation, known as the "prior substantiation doctrine," occurs when courts refuse to find in favor of class action plaintiffs when the FTC has already negotiated a settlement with a retailer regarding unsubstantiated advertise-

179. *See id.* (providing suggestions of how scammers can implement new schemes through online means or do traditional scams more easily).

180. *See* FTC Complaint, *supra* note 13, at 5 (listing ways in which Reebok shared EasyTone ads). R

181. *See generally* Susan E. Gindin, *Nobody Reads Your Privacy Policy or Online Contract? Lessons Learned and Questions Raised by the FTC's Action Against Sears*, 8 NW. J. TECH & INTELL. PROP. 1, 21-25 (summarizing Commission's programs to educate and target online advertisers).

182. *See* Dana Rosenfeld & Daniel Blynn, *The "Prior Substantiation" Doctrine: An Important Check on the Piggyback Class Action*, 26 A.B.A. ANTITRUST SEC. 68, 68 (2011), *available at* http://www.kelleydrye.com/publications/articles/1537/_res/id=Files/index=0/Fall11-RosenfeldC.pdf (suggesting that consumers are unable to or would gain no benefit from bringing class action lawsuits against retailers who disseminate unsubstantiated ads).

183. *See id.* (implying that consumers may have little recourse from advertisers).

184. *See* Fraker v. Bayer Corp., No. CV F 08-1564 AWI GSA, 2009 WL 5865687, at *8 (E.D. Cal. Oct. 6, 2009) (holding that in Eastern District of California private plaintiffs have no right to bring cause of action regarding violation of law within FTC jurisdiction, including unsubstantiated advertising); *see also* Rosenfeld & Blynn, *supra* note 182, at 71 ("[P]rivate plaintiffs have filed a number of recent state law consumer protection and false advertising class actions, which do little if anything more than lift allegations directly from the FTC pleadings and FDA warning letters. . . . [C]ourts, however, have uniformly rejected this characterization."). R

ments.[185] Courts are unwilling to allow plaintiffs to "piggyback" off of FTC complaint charges to obtain independent recovery.[186] Consequently, the Commission's regulatory role is more important than ever in ensuring consumers are protected, as they may be unable to assert their own claims in the court system that they have been harmed by unsubstantiated advertisements.[187]

B. Historic and Continuing FTC Interest in Regulating Fitness Products

The FTC also needs to create fitness substantiation guidelines because of its longstanding and general interest in regulating products that claim to help users with weight loss.[188] Much of this regulatory interest is due to the pervasiveness of the diet and exercise industry continually inundating the market with newer and better products.[189] Additionally, as Americans struggle to balance busy lives and achieve weight loss, many people seek quick fixes, short-

185. *See Fraker*, 2009 WL 5865687, at *5 ("[T]he entirety of Plaintiff's claims of wrongdoing are based on factual allegations made in, on inferred from, either the Consent Decree or the FTC Order. The court can find no independently acquired evidence that would tend to support Plaintiff's central allegations of deceptive advertising.").

186. *See* Rosenfeld & Blynn, *supra* note 182, at 68 (describing "piggybacking" as class action plaintiffs with complaints "virtually identical to or rely[ing] heavily upon FTC complaints or federal Food and Drug Administration warning letters"). R

187. *See id.* at 71 (noting Commission's efforts to bring enforcement actions against large-scale advertisers for unsubstantiation). Additionally, there has been at least one case suggesting that plaintiffs may not be able to prevail against an advertiser in a Lanham Act claim simply by asserting that the advertiser had not substantiated a claim. *See* Precision IBC, Inc. v. PCM Capital, LLC, Civil Action No. 10–0682–CG–B, 2011 WL 2728467, at *3 (S.D. Ala. July 12, 2011) (holding that plaintiffs must prove falsity as well as unsubstantiation); *see also* Rosenfeld & Blynn, *supra* note 182, at 71 (providing Precision IBC example as analogous to non-Lanham Act situations). The FTC technically also has the burden to prove that the challenged advertisement is false, but often this situation is not realized because many advertisers faced with FTC warning letters or complaints choose to resolve the situation cooperatively and the matter does not progress to a trial setting in which the FTC would have to meet the burden of proving falsity. *See id.* at 69 (discussing Commission's burden of proof but relative probability that situation would not reach that level). *But see* F.T.C. v. Direct Mktg. Concepts, Inc., 624 F.3d 1, 8 (1st Cir. 2010) (suggesting that FTC is not required to prove falsity to prevail against defendant advertiser on unsubstantiation claim). R

188. *See FTC Announces "Operation Waistline"*, *supra* note 126 (reporting that Commission has "brought nearly 140 enforcement actions against weight loss companies" between 1927 and 1997). R

189. *See* FTC WEIGHT-LOSS ADVERTISING REPORT, *supra* note 2, at vii ("Once the province of supermarket tabloids and the back sections of certain magazines, over-the-top weight loss advertisements promising quick, easy weight loss are now pervasive in almost all media forms."). R

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cuts, or merely efficient ways to lose weight faster.[190] All of this has precipitated the FTC's decades-long interest in ensuring that products relating to weight loss and improved exercise performance are properly substantiated.[191] The history of FTC enforcement actions indicate that toning shoes fall within the agency's strategic regulation of fitness products, which are "devices" that help users lose weight, improve muscle mass and strength, or tone specific areas of the body.[192]

Since the 1990s, the FTC has commissioned panels to investigate trends in weight loss advertising, created large-scale enforcement schemes, and joined with other regulatory agencies and non-government groups to research weight loss advertising and educate consumers.[193] The increasing amounts of FTC penalties (and targeting of large national retailers of fitness products) also demonstrates the agency's building interest in regulating substantiation in this area: there is a massive difference in comparing the slimming shoe insole penalties in the late 1990s for $40,000 and $100,000 and the Reebok penalty of $25 million.[194]

190. *See Case #5263: Reebok International, Ltd.*, *supra* note 45, at 3 (citing "backdrop" of Better Business Bureau investigation of EasyTone shoes that "[m]illions of women struggle to find time to exercise. Consequently, a walking shoe that promises to deliver tightening and toning in the legs and glutes by simply walking around in them doing the course of the day is very appealing."). R

191. *See FTC Announces "Operation Waistline"*, *supra* note 126 (referencing in press release comments from former BCP director about why consumers may be "easy prey" for deceptive weight-loss advertising because of health and obesity concerns, which is why FTC has taken action). *But see Joel Stein, Miracle-Diet Ads Lie? Well, Duh!*, TIME (Sept. 30, 2002), http://www.time.com/time/magazine/article/0,9171,1003330,00.html (assessing Operation Waistline report and suggesting that most people are aware, without FTC investigation, about limitations of weight-loss pills and related claims). R

192. *See* FTC Complaint, *supra* note 13, at 8 ("For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Defendant's purported toning footwear products, including EasyTone and RunTone footwear products, are 'device[s]' as defined in Section 15(d) of the FTC Act, 15 U.S.C. § 55(d)."); Guildwood Direct Ltd., 123 F.T.C. 1558, 1558 (1997) (defining shoe insole product as "device" under FTC Act); *see also FTC Puts Exercise Device Weight-Loss Claims On a Diet*, FED. TRADE COMM'N (June 17, 1997), http://www.ftc.gov/opa/1997/06/workout.shtm (referring to exercise machines as "devices"); Pump Fiction, *supra* note 163, at 2 (warning consumers about home exercise machines and products claiming "spot reduction"). R R

193. *See, e.g.*, FTC WEIGHT-LOSS ADVERTISING REPORT, *supra* note 2, at iv (discussing partnership among government agencies and non-profit groups to investigate weight loss advertising); *FTC Announces "Operation Waistline"*, *supra* note 126 (celebrating jointly-released consent orders regarding unsubstantiated ads for diet and fitness products). R R

194. *Compare Guildwood*, 123 F.T.C. at 1573 (citing amount of penalty) *and* Bodywell, Inc., 123 F.T.C. 1577, 1592 (1997) (stating amount of consumer redress), *with* Reebok Stipulated Final Judgment, *supra* note 70, at 7-8 (noting how much Reebok must pay in escrow for consumers). R

However, the pressing need for fitness substantiation guidelines arose when the agency shifted from ignoring fitness claims in the *Iovate* consent order in 2010 to focusing an entire investigation on such fitness claims through the investigation of Reebok's advertisements in 2011.[195] In *Iovate*, the FTC did not require the company to substantiate claims relating to the disputed dietary supplements' effectiveness in enhancing "muscle mass" or improving a user's athletic performance and recovery.[196] In contrast, when investigating Reebok's fitness claims only one year later, the FTC focused its investigation on the athletic performance of its EasyTone shoes and how those shoes could help wearers improve muscle tone.[197] The emphasis on substantiating Reebok's claims indicates that the FTC had more concern than it did the year before for how consumers can be harmed by unsubstantiated ads for fitness products.[198]

C. Current Lack of Concrete Guidance for Substantiating Fitness Claims

The FTC's "reasonable basis" standard for substantiating claims is relatively flexible and fact-specific, as the agency itself has admitted.[199] It is undisputed, however, that fitness products at least require the FTC's heightened standard for substantiation of health and safety claims: claims of those products' benefits must be supported by "competent and reliable scientific evidence."[200] This is evidenced by the Commission's application of the standard to a

195. *Compare* Iovate Stipulated Judgment, *supra* note 147, at 8 (omitting "bodybuilding" and muscle mass improvement claims from requirement to comply with competent and reliable scientific evidence), *with* Reebok Stipulated Final Judgment, *supra* note 70, at 5-6 (focusing first count of consent order on company's claims about product's ability to increase muscle tone). R R

196. *See* Iovate Stipulated Judgment, *supra* note 147, at 7-8 ("Defendants . . . are hereby permanently restrained and enjoined from making . . . any representation . . . other than claims regarding bodybuilding and exercise performance . . . ."). R

197. *See* FTC Complaint, *supra* note 13, at 4 (summarizing Reebok's business activities through its representation that EasyTone shoes improve muscle tone and increase athletic performance). R

198. *See Reebok to Pay $25 Million in Customer Refunds To Settle FTC Charges of Deceptive Advertising of EasyTone and RunTone Shoes*, *supra* note 20 (quoting BCP director in Reebok settlement press release: "The FTC wants national advertisers to understand that they must exercise some responsibility and ensure that their claims for fitness gear are supported by sound science."). R

199. *See* Shaheen & Mudge, *supra* note 118, at 66 (discussing FTC responses to claims that substantiation standard is overly flexible). R

200. *See* Reebok Stipulated Final Judgment, *supra* note 70, at 5-6 (requiring "competent and reliable scientific evidence" regarding Reebok advertisements). R

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myriad of weight loss products, including abdominal exercise belts, shoe insoles, and exercise machines.[201] The FTC, however, has readily admitted that it does not have regulations in place defining competent and reliable scientific evidence, and that it has no wish to promulgate any regulations on the topic.[202] Agency personnel have stated that the FTC prefers the flexibility available when there are no stringent standards, as this allows for individualized review of advertisers' claims in light of the available scientific evidence.[203] Additionally, officials have stated that they are concerned that a strict standard would set the bar higher than necessary for advertisers to scientifically substantiate their claims.[204]

As a result of this flexibility, however, the current FTC guidance is insufficient and may confuse fitness advertisers trying to ensure that their ads have adequate scientific substantiation.[205] At this time, fitness retailers can only rely on a limited number of resources to ensure their compliance with the "competent and reliable scientific evidence" doctrine.[206] Such sources include official publications that address substantiation as a small subset of other advertising issues, limited case law about advertising substantiation,

201. *See, e.g.*, Telebrands Corp. v. F.T.C., 457 F.3d 354 (4th Cir. 2006) (citing FTC order prohibiting defendants from marketing "Ab Force" without "competent and reliable scientific evidence"); Guildwood Direct Ltd., 123 F.T.C. 1558, 1570 (1997) (defining competent and reliable scientific evidence); Decision and Order at 2-3, In re NordicTrack, Inc., Docket No. C-3675 (June 17, 1996), *available at* http://www.ftc.gov/os/1996/06/nordic_d.pdf (requiring competent and scientific evidence standard for defendant's ads about rate and amount of weight loss from using its products). The Commission has also applied this standard to a variety of other weight loss products, including dietary supplements and patches that adhere to the skin to supposedly aid in weight loss. *See, e.g.*, F.T.C. v. Phoenix Avatar, LLC, No. 04 C 2897, 2004 WL 1746698 (N.D. Ill. July 30, 2004) (requiring "competent and reliable scientific evidence" to lift injunction on advertisers of diet patch); F.T.C. v. Nat'l Urological Grp., 645 F. Supp.2d 1167 (N.D. Ga. 2008) (finding that defendants had not met standard with regard to dietary supplement advertising).

202. *See Advertising Claims for Dietary Supplements: Denial for Petition of Rulemaking*, *supra* note 19 ("Under the FTC Act, there is no regulatory scheme for the pre-market review and approval of advertising claims for products or services, including dietary supplements."). R

203. *See id.* (discussing benefits of lacking substantiation standards).

204. *See id.* ("The Commission has determined that further refinement of the standard through rulemaking might result in a more rigid standard that, in some instances, could be higher than necessary to ensure adequate scientific support for certain specific claims.").

205. *See generally* Shaheen & Mudge, *supra* note 118 (discussing recent changes to FTC policy and possibility that agency will continue to modify standards). R

206. *See generally Advertising Claims for Dietary Supplements: Denial for Petition of Rulemaking*, *supra* note 19 (listing variety of sources that advertisers can use in creating weight loss claims). R

FTC personnel statements and presentations, and individual consent orders binding only on those advertisers.[207] The FTC has also recommended that advertisers utilize information available publicly on the Commission's business education website about generally acceptable marketing practices.[208]

Nevertheless, these sources are not specific enough to provide fitness advertisers with enough information to substantiate their claims about the performance and weight loss benefits of fitness products.[209] For one, the existing case law and literature has generally not discussed how fitness advertisers specifically can properly substantiate claims about how their products improve sports performance, increase muscle tone, or encourage weight loss; instead, existing law focuses on substantiating advertisements for dietary supplements.[210] Additionally, the Reebok consent order indicates that a single fitness product may need to be substantiated by different levels of evidence depending on what kind of claim is made in an advertisement.[211]

For example, the consent order in the Reebok case specified two different definitions of "competent and reliable scientific evidence" depending on what information Reebok wanted to advertise.[212] In Section I of the settlement, the FTC prohibited Reebok from making claims that EasyTone products were "effective in

207. *See id.* (presenting FTC's advice in lieu of creating standards).

208. *See id.* (recommending online resources "in addition" to case law, FTC official guides, and personnel statements).

209. *See generally* Roscoe B. Starek, III & Lynda M. Rozell, *The Federal Trade Commission's Commitment to On-Line Consumer Protection*, 15 J. MARSHALL J. COMPUTER & INFO. L. 679, 695-96 (1997) (asserting that despite benefits consumer education campaigns can have on stopping deceptive online advertising, they cannot supplant need for FTC enforcement actions). *But see Reebok to Pay $25 Million in Customer Refunds To Settle FTC Charges of Deceptive Advertising of EasyTone and RunTone Shoes*, *supra* note 20 (suggesting in FTC press release about Reebok settlement that consumers should be proactive in "evaluat[ing] advertising claims" and providing link to consumer education materials). R

210. *See, e.g.*, Anne V. Maher, *The FTC's Regulation of Advertising*, 65 FOOD & DRUG L.J. 589 (2010) (exploring broad concept of FTC advertising regulation through food and drug products); John E. Villafranco & Katie Bond, *Dietary Supplement Labeling and Advertising Claims: Are Clinical Studies on the Full Product Required?*, 64 FOOD & DRUG L.J. 43 (2009) (evaluating substantiation standard with regard to dietary supplements); Jack E. Karns & Alan C. Roline, *The Federal Trade Commission's Deception Policy in the Next Millennium: Evaluating the Subjective Impact of Cliffdale Associates*, 74 N.D. L. REV. 441 (1998) (considering substantiation requirements exemplified by chemically-derived products advertising).

211. *See* Reebok Final Stipulated Judgment, *supra* note 70, at 5-7 (providing two different standards of substantiation for same EasyTone products depending on what advertisement claims). R

212. *See id.* (comparing varied requirements for "competent and reliable scientific evidence").

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strengthening muscles" or would "result in [a] quantified percentage or amount of muscle tone or strengthening" unless Reebok had competent and reliable scientific evidence.[213] Section I's competent and reliable scientific evidence was required to include "at least one Adequate and Well-Controlled Human Clinical Study" evaluated in light of all other available scientific evidence.[214]

In contrast, Section II of the settlement prohibited Reebok from making any other EasyTone health or fitness-related claims concerning "muscle tone and/or muscle activation" unless those claims were not misleading and were supported by competent and reliable scientific evidence.[215] Under Section II, competent and reliable scientific evidence is defined as "tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results."[216] The disparity between Sections I and II as to what constitutes competent and reliable scientific evidence, as well as the lack of explanation for why some health and safety claims require a clinical study and others allow more flexible data, underscores the need for official FTC standards about adequate substantiation of fitness advertising.[217] Furthermore, it is unfair to advertisers that the FTC expects them to substantiate claims with scientific evidence (with threats of monetary penalties and injunctions), but refuses to issue standards about what data and studies would qualify as proper substantiation to the Commission.[218]

D. Inapplicability of Current Resources for Fitness Advertisers

The FTC can more effectively prohibit false and deceptive weight loss advertising by issuing official guides specifically about substantiation of fitness and performance-related claims in adver-

213. *See id.* at 5 (defining prohibition on advertising under Section I of order).

214. *See id.* at 5-6 (detailing requirements for competent and reliable scientific evidence for claims relating to muscle tone or percentage of toning).

215. *See id.* at 5 (including all other claims that Reebok could make regarding benefits of EasyTone shoes and apparel).

216. *See id.* at 6-7 (requiring less stringent standard for substantiating other health and fitness claims).

217. *See generally* Karns & Roline, *supra* note 210 (presenting multiple case studies of what FTC has accepted and rejected as proper evidence to substantiate health claims). R

218. *See Advertising Claims for Dietary Supplements: Denial for Petition of Rulemaking*, *supra* note 19 (rejecting pharmacies' petition to FTC to promulgate requirements for substantiation). R

tisements.[219] The Commission has used its statutory authority to promulgate a number of "industry guides" with the purpose of helping advertisers comply with the law and encouraging "voluntary and simultaneous abandonment of unlawful practices by members of industry."[220] Available codified guides include guides on the use of terms such as "free" in advertisements, environmental advertising, and the use of testimonials and endorsements.[221] Aside from codified rules developed through public notice-and-comment procedures, the Commission has also published internally prepared advertising guidance with comprehensive suggestions and examples similar to those in the industry guides.[222] However, the FTC has published neither an industry guide nor an unofficial guide for advertiser use to learn about substantiation of claims related to the use of fitness products.[223]

Additionally, existing FTC publications are insufficient for fitness advertisers because they do not discuss how these advertisers should interpret substantiation requirements for their specific claims.[224] The Commission's guiding document on substantiation, the *FTC Policy Statement Regarding Advertising Substantiation*, is nearly thirty years old and does not include subsequent developments in substantiation law, including the competent and reliable scientific evidence standard for health claims.[225]

219. *See generally FTC Policy Statement on Deception*, FED. TRADE COMM'N (Oct. 14, 1983), http://www.ftc.gov/bcp/policystmt/ad-decept.htm ("The Commission intends to enforce the FTC Act vigorously. We will investigate, and prosecute where appropriate, acts or practices that are deceptive.").

220. *See* C.F.R. T. 16, ch. 1, subch. B, pt. 17 (2011) (stating purpose of industry guides); *see also* 15 U.S.C. § 46(g) (2006) (granting Commission statutory authority to issue regulations to carry out FTC Act).

221. *See, e.g.*, 16 C.F.R. § 251.1 (2011) (establishing recommendations for legality of advertising product with claim that such product is "free"); 16 C.F.R. § 260.1 (2011) (introducing guidelines for voluntary compliance with law based on environmental marketing); 16 C.F.R. § 255.0 (2011) (providing introduction for industry guide about endorsements and testimonials).

222. *See Advertising Guidance*, FED. TRADE COMM'N, http://www.ftc.gov/bcp/guides/guides.shtm (last visited Feb. 19, 2012) (collecting industry guides also available in Code of Federal Regulations along with FTC-prepared publications).

223. *See Advertising Claims for Dietary Supplements: Denial for Petition of Rulemaking*, *supra* note 19 (listing existing sources of guidance that advertisers of weight loss products can use in determining how to substantiate claims). R

224. For a more detailed discussion of how existing resources do not adequately help fitness advertisers consider the FTC's substantiation standard, see *supra* notes 205-211 and accompanying text. R

225. *See FTC Policy Statement*, *supra* note 19 (referencing importance of "reasonable basis" requirement for advertising claims and general ideas about how advertisers can substantiate product claims); Novartis Corp. et al., 127 F.T.C. 580, 580 (1999) (determining that health and safety claims must be substantiated by competent and reliable scientific evidence). For a more detailed discussion of the com- R

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The most similar guidance available is the Commission's *Dietary Supplement Advertising Guide*, a 1998 document directed to manufacturers of oral dietary supplements.[226] Although this unofficial publication is a comprehensive document with substantiation guidance about general weight loss claims, it does not discuss how to substantiate claims important to fitness advertising, such as improving muscle tone or athletic performance.[227] Similarly, as dietary supplements are chemical compounds, unlike fitness products, the document's recommendations about clinical trials (such as use of animal trials or limited epidemiological studies) are inapplicable.[228] Furthermore, this document is unsuited to fitness advertisers, because unlike dietary supplement retailers, they have not been subjected to the massive scrutiny and public outcry associated with the disease-related dangers of taking dietary supplements.[229]

Similarly, the newly created 2009 *Guides Concerning the Use of Endorsements and Testimonials in Advertising* likewise provides little guidance for fitness advertisers, as this document merely reiterates that claims accompanied by testimonials must be supported by competent and reliable scientific evidence.[230] These guidelines came about when the FTC decided to modify its policies from 1980 as part of a regulatory review program to determine if the earlier doc-

petent and reliable scientific evidence standard, see *supra* note 122 and accompanying text. **R**

226. *See Dietary Supplements: An Advertising Guide for Industry*, FED. TRADE COMM'N, at 1-2 (Apr. 2001), http://business.ftc.gov/sites/default/files/pdf/bus09-dietary-supplements-advertising-guide-industry.pdf [hereinafter *Dietary Supplement Advertising Guide*] (introducing Guide and its purposes).

227. *See id.* at 8-14 (producing guidelines about dietary supplement substantiation).

228. *See id.* at 10 (suggesting alternatives to full-scale clinical trials of dietary supplements).

229. *See, e.g.*, Cassandra Burke Robertson, *Separating Snake Oil from Therapeutic Supplements: The Nexus Between Litigation and Regulation in the Dietary Supplement Industry*, 35 U. TOL. L. REV. 317 (2003) (recommending increased litigation to reduce injuries caused by dietary supplements); Katharine A. Van Tassel, *Slaying the Hydra: The History of Quack Medicine, The Obesity Epidemic and the FDA's Battle to Regulate Dietary Supplements Marketed as Weight Loss Ads*, 6 IND. HEALTH L. REV. 203 (2009) (considering health-related reasons why government should increase regulation of dietary supplements); Richard Potomac, Student Article, *Are You Sure You Want to Eat That?: U.S. Government and Private Regulation of Domestically Produced and Marketed Dietary Supplements*, 23 LOY. CONSUMER L. REV. 54 (2010); *see also* Natasha Singer, *Here's to Your Health, So They Claim*, N.Y. TIMES, Aug. 28, 2011, at BU1, *available at* http://www.nytimes.com/2011/08/28/business/supplement-drugs-may-contain-dangerous-ingredients.html (referencing research stating that dietary supplements can include illegal amphetamines and steroids and cause kidney failure, strokes, drug addiction, heart attacks, and death).

230. *See* 16 C.F.R. § 255.1(d) (2011) ("Advertisers are subject to liability for false or unsubstantiated statements made through endorsements. . . .").

ument had provided useful guidance to advertisers or needed changes because of general flaws or the passage of time.[231] The new guides about endorsements and testimonials, however, do not provide any additional requirements for testing of products: they only note that if an endorser makes a claim, the retailer is responsible for the claim, which thus needs to be substantiated.[232]

VI. PUTTING SHOES ON ONE FOOT AT A TIME: RECOMMENDATIONS FOR FITNESS SUBSTANTIATION GUIDELINES

This section suggests several ways that the FTC can use its regulatory authority and post-Reebok publicity to revitalize its enforcement schemes against unsubstantiated fitness advertising by creating official guidelines about substantiating fitness claims.[233] Despite its disinterest in creating industry-wide requirements for substantiation, the FTC is fully capable of establishing a guide with defined substantiation parameters for fitness products claiming health and safety benefits because of its success with other advertising-related publications.[234] The Commission has the resources to undertake such a project, and has previously updated its advertising guidelines after determining that versions from decades past were insufficient in requiring advertisers to follow the law.[235] Addition-

231. *See* Guides Concerning the Use to Endorsements and Testimonials in Advertising, 72 Fed. Reg. 2214, 2214 (Jan. 18, 2007) (publishing request for public comment about effects and recommended changes to endorsement guides).

232. *See* 16 C.F.R. § 255.2(a) (2011) (providing guidelines for consumer endorsement of products). The rule states:

> Therefore, the advertiser must possess and rely upon adequate substantiation, including, when appropriate, competent and reliable scientific evidence, to support such claims made through endorsements in the same manner the advertiser would be required to do if it had made the representation directly, i.e., without using endorsements. Consumer endorsements themselves are not competent and reliable scientific evidence.

Id. (holding advertiser responsible for claims made by consumer testimonials).

233. For a more detailed discussion of what the FTC can include in the proposed fitness substantiation guidelines, see *infra* notes 240-284 and accompanying text. **R**

234. *See, e.g.*, *Dietary Supplement Advertising Guide*, *supra* note 226, at 1-2 (establishing purposes and motivations of advertising guide); *Guides Concerning the Use of Endorsements and Testimonials in Advertising*, FED. TRADE COMM'N, at 1 (Dec. 1, 2009), http://www.ftc.gov/os/2009/10/091005revisedendorsementguides.pdf [hereinafter *Revised Endorsement and Testimonial Guides*] (explaining why agency created guidelines for these claims); *see also Advertising Claims for Dietary Supplements: Denial for Petition of Rulemaking*, *supra* note 19 (recommending that advertisers look to already-existing FTC publications and guidelines to help substantiation). **R** **R**

235. *See FTC Publishes Final Guides Governing Endorsements, Testimonials*, *supra* note 164 (providing reasons why 1980 guides regarding endorsements and testimonials required updating). **R**

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ally, the agency has recently required individual advertisers to adhere to identical standards, which indicates that it should produce official substantiation standards for the overall good of the industry.[236]

Although existing guidance is not sufficient on its own to help fitness product advertisers understand what they must do to substantiate claims, these documents do provide some suggestions as to the content and form of the proposed fitness substantiation guidelines.[237] For example, the proposed standards below implement the language the FTC has used in its most recent consent orders regarding the number and quality of required clinical trials.[238] Similarly, the proposed fitness substantiation guidelines include suggestions about the credibility of studies that are from the FTC's unofficial and official guidance, as well as from the advertising industry's self-regulatory practices.[239]

A. Requiring Two Controlled, Double-Blind Studies to Substantiate Claims

The first thing the FTC should do in the proposed substantiation guidelines is identify which fitness claims require precise scientific testing to substantiate advertisements, and which claims can be substantiated with other types of evidence.[240] In general, the Commission has been more concerned about substantiating objective performance claims instead of subjective opinion claims.[241] Based

236. *See* Shaheen & Mudge, *supra* note 118, at 66-67 (discussing impact of Nestlé and Iovate consent orders). For a more detailed discussion about the FTC's recent consent orders requiring identical substantiation evidence, see *supra* notes 142-159 and accompanying text. R

237. For a more detailed discussion about why existing FTC guidance is insufficient to help fitness advertisers substantiate claims, see *supra* notes 219-232 and accompanying text. R

238. For a more detailed discussion about the importance of the language in the FTC's recent consent orders, see *infra* notes 240-255 and accompanying text. R

239. For a more detailed discussion about ensuring that research used to substantiate fitness claims are credible, see *infra* notes 256-284 and accompanying text. R

240. *See* Grebow, *supra* note 142 (identifying disparity between FTC's specific consent order language and agency's position that only official standard is competent and reliable scientific evidence). R

241. *See* Dorothy Cohen, *The FTC's Advertising Substantiation Program*, 44 J. MARKETING 26, 26 (1980) (comparing importance to FTC of advertiser claiming product provides pleasurable taste versus has ability to accomplish specific goal); *Advertising Practices Frequently Asked Questions*, FED. TRADE COMM'N, 6 (Apr. 2001), http://business.ftc.gov/sites/default/files/pdf/bus35-advertising-faqs-guide-small-business.pdf (comparing types of claims that FTC would view as more important to regulate – those that claim health and safety benefits, or those that consumers would be unable to evaluate – as opposed to claims that consumers can validate on their own); *see also* Lili Vianello, *Customer Service: FTC Advertising Guidelines: A Matter*

on this, the FTC needs to provide specified guidance to clarify exactly what kind of fitness and performance claims require clinical testing as compared to other acceptable forms of substantiation.[242] Recent consent orders for health and safety claims, as well as the Reebok consent order, indicate that specific performance claims, such as how a product will increase weight loss or muscle tone, or stave off sickness, require strictly defined clinical testing.[243]

These consent orders have separated into categories "prohibited representations" of specific performance versus "other claims."[244] The two categories then require differing amounts of substantiation: specific claims require human clinical trials while general claims require only non-specified studies, research, or other types of evidence.[245] The similar language in each of the consent orders about clinical trials indicates that the FTC has advanced a clinical trial standard that advertisers must use to substantiate spe-

of Law, Ethics, and Trust, COLUMBIA BUS. TIMES (June 13, 2008), http://columbiabusinesstimes.com/1504/2008/06/13/customer-service-ftc-advertising-guidelines-a-matter-of-law-ethics-and-trust/ ("The FTC will pay very close attention to objective claims like, 'Such-and-Such juice helps prevent cancer,' but less attention to more subjective claims like, 'So-and-So biscuits are delicious.'"). For example, in the Reebok settlement, the FTC focused on the advertisers' claims that EasyTone shoes were better able to improve a user's muscle tone and strength more than a typical walking shoe. *See* FTC Complaint, *supra* note 13, at 4 (detailing general basis for complaint against performance claims). The Commission also took specific note of Reebok's "28-11-11" claim regarding specific percentages of muscle tone allegedly gained from using EasyTone shoes. *See id.* at 5-6 (referencing Reebok's percentage-based claims as focus of suit). **R**

242. *See generally* Shaheen & Mudge, *supra* note 118, at 69 (discussing how FTC's recent consent orders indicate movement toward official standard). *But see* John E. Villafranco et al., *The FTC's New Take on Health-Related Advertising: What Companies Facing FTC Enforcement Need to Know*, KELLEY DRYE & WARREN LLP, 28 (September/October 2010), http://www.kelleydrye.com/publications/articles/1403/_res/id=Files/index=0/FTC%27s%20New%20Take%20on%20Health-Related%20Advertising_Oct%202010.pdf (suggesting that advertisers possibly subject to FTC enforcement action should support broad definition of substantiation instead of specific factors). **R**

243. *See, e.g.*, Iovate Stipulated Judgment, *supra* note 147, at 6-7 (requiring clinical trials for claims of weight loss or "rapid" weight loss); Nestlé Healthcare Nutrition, Inc., 151 F.T.C. 1, 6-7 (2011) (demanding clinical trials for claims that BOOST drinks precluded certain childhood illnesses). **R**

244. *See* Reebok Final Stipulated Judgment, *supra* note 70, at 5-7 (separating representations about "strengthening claims and quantified muscle toning claims" from "other health or fitness-related claims"); Iovate Stipulated Judgment, *supra* note 147, at 6-7 (distinguishing "weight-loss claims" and "other health-related claims"). **R** **R**

245. *See* Reebok Final Stipulated Judgment, *supra* note 70, at 5-7 (requiring different types of evidence based on type of claim); Iovate Stipulated Judgment, *supra* note 147, at 6-7 (providing two standards for substantiation evidence). **R** **R**

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cific health claims.[246] Clinical trials must be conducted with human subjects, done independently of each other by different, non-associated researchers, and their results must comport with other available evidence to be appropriate substantiation.[247] Additionally, all of the consent orders define clinical trials to be "randomized, controlled, [ ] blinded" and conducted by a researcher "qualified by training and experience."[248] Generally, researchers and the FTC consider a randomized, blinded clinical trial as the "gold standard" to test hypotheses.[249] The Commission required this for Iovate's claims regarding weight loss, Nestlé's claims about diarrhea, and Reebok's muscle toning claims.[250] Since the FTC has required the same clinical testing requirements in its largest and most recent consent orders, it should make this information available through a guidance document to other manufacturers who may make the same claims for the sake of uniformity, predictability, and general awareness.[251]

However, in the Reebok order, the FTC only required that the company provide one well-controlled clinical trial, compared to the

246. *See* Grebow, *supra* note 142 ("However, with more consent decrees asking for two randomized, placebo-controlled, human clinical studies as evidence, should companies nevertheless assume that this is the FTC's new substantiation threshold?"); Shaheen & Mudge, *supra* note 118 ("[The Iovate and Nestlé] consent orders require that companies conduct two double-blind, placebo-controlled clinical studies on humans using the advertised product or "essentially equivalent" product to substantiate certain types of claims."). R R

247. *See* Iovate Stipulated Judgment, *supra* note 147, at 7 (requiring safeguards to protect integrity of study); *Nestlé*, 151 F.T.C. at 7 (placing burden to substantiate and ensure quality of trial on defendants); Reebok Final Stipulated Judgment, *supra* note 70, at 5-6 (noting specific requirements). R R

248. *See* Reebok Final Stipulated Judgment, *supra* note 70, at 4 (defining "adequate and well-controlled human clinical study"). The Nestlé and Iovate consent orders similarly require placebo-controlled and blinded studies conducted by scientists with requisite training and knowledge. *See Nestlé*, 151 F.T.C. at 5 (specifying that clinical trial standard in order is to be followed as closely as possible so long as such trial is "effective" and "ethical"); Iovate Stipulated Judgment, *supra* note 147, at 4 (stating similar language to Reebok consent order regarding clinical trials). R R

249. *See* Shaheen & Mudge, *supra* note 118, at 66 ("Overall, a randomized, blinded clinical trial is considered "gold standard" in scientific research."). R

250. *See* Iovate Stipulated Judgment, *supra* note 147, at 7 (detailing terms of clinical trials required to substantiate weight loss claims); *Nestlé*, 151 F.T.C. at 6-7 (requiring clinical trial standard to substantiate illness claims); Reebok Final Stipulated Judgment, *supra* note 70, at 5-6 (specifying terms of clinical trials to substantiate advertising muscle tone improvement). R R

251. *See generally* Grebow, *supra* note 142 (discussing effects of FTC specific consent orders on future advertising actions). R

Nestlé and *Iovate* requirement of two clinical trials for their claims.[252] Such a disparity in the number of required trials is not comprehensible unless the FTC specifically clarifies in guidelines why muscle toning and fitness claims should be held to a lower standard than weight loss or disease prevention.[253] Additionally, the need for two studies is especially important given the FTC's high-profile Reebok consent order and the FTC's subsequent warning that fitness retailers must be accountable to advertising laws.[254] As indicated in the following sections, general principles regarding scientific research to increase credibility of such research also militate toward requiring two studies for substantiating fitness claims.[255]

B. Rejecting Outlier Studies in Favor of the "Totality of the Evidence"

The language in the FTC's recent consent orders, as well as agency history, indicates that the FTC should clearly state in fitness substantiation guidelines that an "outlier" study is unacceptable on its own to substantiate a claim that the product provides a fitness or performance benefit.[256] Such claims should not be solely based on such an outlier study, defined as research with results that conflict with the weight of other scientific evidence.[257] BCP director David Vladeck noted this concern for substantiating advertisements in a 2009 speech stating that, "One outlier study should not be the sole basis of support for a claim that a product will confer a benefit –

252. *Compare* Reebok Final Stipulated Judgment, *supra* note 70, at 6 (ordering one clinical trial) *with* Iovate Stipulated Judgment, *supra* note 147, at 7 (demanding two clinical trials). R R

253. *See Reebok to Pay $25 Million in Customer Refunds To Settle FTC Charges of Deceptive Advertising of EasyTone and RunTone Shoes*, *supra* note 20 (emphasizing FTC officials' statements of agency's role in curbing unlawful actions of fitness advertisers). R

254. *See id.* (emphasizing FTC's "ongoing effort to stem overhyped advertising claims").

255. For a discussion of other factors indicating that two clinical trials are necessary for fitness-related claims, see *infra* notes 256-265 and accompanying text. R

256. *See, e.g.*, Nestlé Healthcare Nutrition, Inc., 151 F.T.C. 1, 7 (2011) (requiring that Nestlé's two clinical studies be "considered in light of the entire body of relevant and reliable scientific evidence"); Iovate Stipulated Judgment, *supra* note 147, at 8 (requiring same consideration of all other available scientific research). R

257. *See Dietary Supplement Advertising Guide*, *supra* note 226, at 14 ("Advertisers should consider all relevant research relating to the claimed benefit of their supplement and should not focus only on research that supports the effect, while discounting research that does not."). It is likely that fitness products' health and safety claims will require more than one study regardless of outlier possibilities, as the FTC has recently been mandating that claims be supported by two human clinical studies. *See* Grebow, *supra* note 142 (noting recent increase recommending more than one study to substantiate claims). R R

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particularly a health benefit."[258] This is particularly important if the FTC continues to require, as it did with Reebok, that fitness and performance claims only require one clinical study to substantiate muscle toning claims.[259] Reebok relied on a single study with only five participants, and the study's results were later contested as having little scientific significance when compared to larger-scale testing of toning shoes.[260]

The agency has had a long history of rejecting a single outlier study as adequate substantiation in advertising for both advertising of weight loss claims and other products.[261] In the FTC's *Dietary Supplements Advertising Guide*, the Commission stated that claims for dietary supplement benefits must be supported by the "totality of the evidence."[262] Likewise, advertisers should avoid choosing one study to support a claim when an equally well-controlled study yields opposite results.[263] The guide suggests that if the "totality of the evidence" does not support the advertiser's claim, then the claim is unsubstantiated and therefore unlawful.[264] The FTC, however, suggests that advertisers should scrutinize seemingly outlier studies before disregarding them and determine if these studies can still be used to substantiate a claim.[265]

258. *See* David C. Vladeck, Dir. FTC Bureau of Consumer Protection, Priorities for Dietary Supplement Advertising Enforcement, *supra* note 143, at 12 (clarifying agency's position regarding development of new substantiation standards). R

259. *See* Reebok Final Stipulated Judgment, *supra* note 70, at 5 (stating that Reebok needs one clinical trial to substantiate EasyTone muscle improvement claims). R

260. *See* Reynolds, *supra* note 48 (collecting research studies about toning shoes and comparing results to Reebok's five-person study). R

261. *See, e.g.*, *Energy Surf Letter*, FED. TRADE COMM'N (Apr. 18, 2002), http://www.ftc.gov/opa/2002/04/energysurfletter.shtm (warning against use of outlier studies to prove automotive product works "up to" certain percentage of success); *Prepared Statement of the Federal Trade Commission on Advertising Trends and Consumer Protection*, FED. TRADE COMM'N, at 10 (July 22, 2010), *available at* http://www.ftc.gov/os/testimony/090722advertisingtestimony.pdf (transcribing testimony of BCP Director David Vladeck, disapproving of outliers in consumer endorsements of weight loss products). Similarly, the FTC has taken the position that "individual experiences" with consumer products may have other explanations and cannot substantiate claims. *See Dietary Supplement Advertising Guide*, *supra* note 226, at 10-11 (discussing validity of personal endorsements). R

262. *See Dietary Supplement Advertising Guide*, *supra* note 226, at 14 (requiring advertisers to consider more than single study for substantiation). R

263. *See id.* ("Wide variation in outcomes of studies and inconsistent or conflicting results will raise serious questions about the adequacy of an advertiser's substantiation.").

264. *See id.* at 14-15 (providing examples of unsubstantiated dietary supplement claims based on conflicting research results).

265. *See id.* at 14 (suggesting tactics that advertisers can use to evaluate "inconsistencies" among study results).

C. Requiring "Real-World" Testing Conditions

The proposed fitness substantiation guidelines should also include detailed instructions about adequate study methodology to ensure that research substantiating fitness advertising claims reflects how a consumer would actually use the product at issue.[266] The FTC should specify for how long research subjects should use fitness product in a study, the population that should use the products in the study (and whether the study population should match the population the advertisement is targeting), and whether the study should be in a controlled laboratory environment or in the "real world" of use.[267] In some situations with regard to athletic shoes or other fitness products, testing their effectiveness outside a laboratory environment may be beneficial to support how the product will actually be used, and the FTC should account for this situation.[268]

Studies to substantiate claims about the benefits of fitness products should also include consideration of what physical and economic harms the products could cause a user.[269] Although fitness products are not associated with the same degree of risk as dietary supplements, retailers should be bound to disclose in advertisements whether their devices, including shoes, apparel, and exercise machines, could cause health problems or injuries.[270] This concern has been implicated slightly with regard to toning shoes; news of Reebok's settlement with the FTC has been accompanied by evi-

266. *See Case #5263: Reebok International, Ltd.*, *supra* note 45, at 1 ("Product testing should reflect consumers' real world experience to ensure performance claims are meaningful."). R

267. *See id.* at 3 (reporting on Better Business Bureau's ("BBB") findings from evaluating scientific method of Reebok-financed study). The BBB researcher was concerned that the Reebok study had only used five subjects to test the toning shoes, and that the study was of a "short duration. *See id.* (noting problems with study). The researcher concluded that this study was therefore insufficient to be "reliable or representative of the target audience." *See id.* (analyzing effect of concerns on study's overall credibility).

268. *See id.* at 1 n.2 (citing another BBB investigation that found that footwear test was adequately substantiated when one of its requirements was that subjects wear shoes as part of everyday lives and avoid changing normal behaviors).

269. *See Dietary Supplement Advertising Guide*, *supra* note 226, at 9 (including physical and economic harms as important to substantiation because they are "consequences of a false claim"). R

270. *See Voluntary Guidelines for Providers of Weight Loss Products of Services*, P'SHIP FOR HEALTHY WEIGHT MGMT., 5 (Feb. 1999), http://business.ftc.gov/sites/default/files/pdf/bus38-voluntary-guidelines-providers-weight-loss-products-or-services.pdf [hereinafter *Voluntary Guidelines*] (recommending disclosure of risks associated with weight-loss programs). For a more detailed discussion of public and scholarly interest in the harms associated with dietary supplements, see *supra* note 229 and accompanying text. R

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dence that some people have encountered injuries from toning shoes.[271]

The proposed substantiation guidelines should include requirements of how long clinical trials of fitness products should last to best replicate repeated, long-term use of a product.[272] In the consent order, the FTC required Reebok's clinical study to last at least six weeks and evaluate performance through "an appropriate measurement tool or tools."[273] In contrast, the study that Reebok actually relied on to claim that EasyTone shoes improve muscle tone more than regular walking shoes did not meet these credibility standards.[274] That study only used five participants who each walked five minutes on a treadmill wearing toning shoes.[275] Such a study did not have the level of credibility to substantiate the claims Reebok made about the benefits of toning shoes, and did not replicate the "real world" in which the product would be used.[276]

D. Avoiding Industry- and Advertiser-Funded Studies

The proposed FTC fitness substantiation guidelines should also discourage advertisers' reliance on self-funded or industry-funded studies to substantiate fitness claims.[277] Requiring several independently-funded and independently-conducted research studies will increase the credibility and quality of future research studies

271. *See* Martin & O'Connor, *supra* note 5, at B1 (reporting on Reebok settlement and including toning shoe hazards). For a more detailed discussion of injuries associated with wearing toning shoes, see *supra* notes 59-62 and accompanying text. R R

272. *See Dietary Supplement Advertising Guide*, *supra* note 226, at 12 (stating that longer dietary supplement studies can help researchers identify safety problems resulting from product). R

273. *See* Reebok Final Stipulated Judgment, *supra* note 70, at 4 (specifying need for established measurement methods, such as dynamometer to measure strength). R

274. *See Case #5263: Reebok International, Ltd.*, *supra* note 45, at 3-4 (summarizing BBB investigation and conclusion that Reebok's study did not adequately provide basis for its claims). R

275. *See id.* at 3-4 (recounting study methodology).

276. *See id.* at 4 ("It is well-established that tests offered to support product performance claims must reflect real world conditions.").

277. *See* 16 C.F.R. § 255.5 (2009) (presenting circumstances in which advertisers must disclose financial relationships to forces behind advertisements, such as paid endorsers); *see also* Tara Parker-Pope, *Firm Body, No Workout Required?*, N.Y. TIMES, Dec. 8, 2009, at D5, *available at* http://www.nytimes.com/2009/12/08/health/08well.html (explaining that toning shoe manufacturers cite studies they funded themselves to support claims of shoes' effectiveness).

used to substantiate claims for fitness products.[278] Consequently, consumers will be better protected against financial loss and personal injury from fitness products, as advertisers' claims will necessarily be validated by a neutral and unbiased third party.[279] This is not to say that advertisers that fund their own research to validate their claims are dishonest; rather, discouraging this practice as a general rule removes implication of bias in the eyes of consumers or the FTC.[280] Protecting consumers by requiring independent and credible research is especially important when it comes to purchasing fitness products based on the trust that consumers already place in athletic brands such as Reebok.[281]

Recommending that advertisers avoid self- or industry-funded research to substantiate claims comports with the FTC's overriding preference for advertisements substantiated by studies that have been peer-reviewed and published in academic journals.[282] Although advertisers are not required to rely on published research to meet substantiation guidelines, the FTC has cited in other contexts how publication and peer review of research makes studies

278. *See Dietary Supplement Advertising Guide*, *supra* note 226, at 10 ("[T]he replication of research results in an independently-conducted study adds to the weight of the evidence."). R

279. *See* David Michaels, *It's Not the Answers that are Biased, It's the Questions*, WASH. POST, July 15, 2008, at HE03, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2008/07/14/AR2008071402145.html (suggesting that "funding effect" would be solved by "de-linking sponsorship and research" because sponsor's relationship to product – either creator or competitor – affects research protocols).

280. *See* Elizabeth Landau, *Where's the Line Between Research and Marketing?*, CNN (Oct. 13, 2010, 1:54 p.m. EDT), http://www.cnn.com/2010/HEALTH/10/13/company.funded.research/index.html (reporting that more companies, other than pharmaceutical companies, have been funding research to substantiate claims about their own products). The author noted that even though companies try to distance themselves from the study's implementation, the overall nature of the relationship counsels consumers to be "wary." *See id.* (discussing how consumers should be skeptical of company- or industry-funded research).

281. *See* Erin Ann O'Hara, *Choice of Law for Internet Transactions: The Uneasy Case for Online Consumer Protection*, 153 U. PA. L. REV. 1883 (2005) (evaluating psychology behind why consumers trust certain brands and how that should factor into legal protections); *see also* Eileen Ambrose, *FTC: Reebok to Pay $25 Million for Deceptive Advertising of Toning Shoes*, BALTIMORE SUN (Sept. 28, 2011), http://articles.baltimoresun.com/2011-09-28/business/bal-consuming-interests-ftc-reebock-20110928_1_easytone-reebok-ftc-s-bureau (citing Reebok spokesman's comments that company will "continue to deliver products that [consumers] trust and love").

282. *See Dietary Supplement Advertising Guide*, *supra* note 226, at 12 (stating benefits of relying on studies that have been evaluated by others); *see also Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Federal Trade Commission*, FED. TRADE COMM'N, http://www.ftc.gov/ogc/sec515/FTC515Guidelines.shtm (specifying FTC's interest in ensuing objective data in all circumstances). R

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more trustworthy for substantiation purposes.[283] Similarly, discouraging possibly biased research studies fits with the FTC's overall goal, evidenced in its consent orders, which ensure that studies substantiating claims adhere to credible and well-known scientific practices.[284]

VII. HAVE CONSUMERS OF FITNESS PRODUCTS WORKED OUT WITH THE REEBOK SETTLEMENT OR BEEN WORKED OVER BY THE FTC?

Even after the FTC crackdown on Reebok, there is no doubt that consumers will continue to purchase fitness products that claim to enhance weight loss, placing their trust in the advertising claims of well-known and credible companies like Reebok.[285] Some commentators have even suggested that the negative publicity from the settlement will not harm Reebok or toning shoe sales in general, because consumers generally like the shoes or simply ignore FTC warnings.[286] Some research has even suggested that the FTC's practice of targeting individual advertising violations and issuing consent orders has a negligible impact on the company's business, which indicates that the FTC's enforcement actions need to serve some other purpose than financial harm.[287] Although Reebok and other toning shoe manufacturers have since ceased advertisements specifying that scientific research support their claims of increased muscle tone, there is always the possibility of new advertisements that could take advantage of the FTC's currently unclear, and therefore flexible, standards.[288]

283. *See Dietary Supplement Advertising Guide*, *supra* note 226, at 12 (reminding that FTC prefers studies that have "received some measure of scrutiny" but that such procedures are not required); *see also Case #5263: Reebok International, Ltd.*, *supra* note 45, at 2 (stating Reebok's position that BBB advisory review through NAD "has never disqualified a study because it was not published"). R R

284. *See* Reebok Stipulated Final Judgment, *supra* note 70, at 5-7 (outlining parameters that all research Reebok utilizes to substantiate its claims must include). R

285. *See Has Reebok Misled With its EasyTone Ads? No 'Butts' About It*, *supra* note 94 (quoting Wharton School of Business professor who states that consumer faith in major retailers always constitutes "risk"); *see also* ElBoghdady, *supra* note 63, at A13 (quoting consultant discussing implications of Reebok settlement: "There are certain industries where all the rulings about claims have not deterred people from buying . . . The promise of a better body from sneakers is analogous to beauty products, where people pay a premium price for hope in a jar."). R R

286. *See* Martin & O'Connor, *supra* note 5, at B1 (referencing opinion of fitness gear commentators speculating on fallout from Reebok settlement). R

287. *See* Higgins & McChesney, *supra* note 97, at 80-81 (summarizing value of targeting individual advertisers if such actions have no effect on advertiser's business profits). R

288. *See id.* (citing Skechers comments that it had stopped supplementing advertising with scientific research findings).

In any event, the highly publicized FTC action against Reebok and the $25 million consumer redress penalty will certainly induce other fitness advertisers to consider what methods they use to support advertising claims.[289] All of the above-mentioned circumstances suggest that the time is suitable for the FTC to overhaul its treatment of the substantiation doctrine and create specific guidelines for fitness product advertisers.[290] The FTC can fulfill one of its major regulatory responsibilities by imposing official agency guidance detailing requirements to substantiate fitness advertising that would deter advertisers from disseminating unsubstantiated advertising and taking advantage of consumers.[291] Individualized consent orders do not provide sufficient guidance and precedent about which studies will properly substantiate future fitness claims.[292] Additionally, if the FTC desires advertisers to self-regulate and take active steps toward ensuring claims with adequate substantiation, it should not leave the advertisers without adequate guidance as to what the Commission would require in a review.[293] Lack of such guidelines is especially puzzling considering the amount of emphasis the FTC has placed on regulating fitness products in the past several decades.[294]

The proposed fitness substantiation guidelines utilize existing FTC guidance and publications to state clearly what fitness advertisers must do to ensure that their claims are supported by credible

289. *See FTC Steps Up Enforcement on Health-Related Claims in Advertising*, DUANE MORRIS (Oct. 28, 2011), http://www.duanemorris.com/alerts/ftc_steps_up_enforcement_on_health-related_claims_in_advertising_4261.html ("While the consent decree applies only to Reebok, it provides key compliance guidance for other advertisers who make health-related claims because it clarifies the FTC's position on substantiating health-related claims . . . ."); Fair I, *supra* note 125 (noting how advertisers can use Reebok settlement as basis for their own future advertising decisions). R

290. For a more detailed discussion of why the FTC's recent behavior indicates the appropriate time to create detailed substantiation guidelines, see *supra* notes 193-198 and accompanying text. R

291. *See Reebok to Pay $25 Million in Customer Refunds To Settle FTC Charges of Deceptive Advertising of EasyTone and RunTone Shoes*, *supra* note 20 (emphasizing FTC's role in ensuring that there is "sound science" behind advertisements). R

292. For a discussion of how FTC requirements in consent orders can be organized into industry-wide guidance, see *supra* notes 240-251 and accompanying text. R

293. *See generally Advertising Claims for Dietary Supplements: Denial for Petition of Rulemaking*, *supra* note 19 (noting advertiser's assertion that it feels that it has been deterred from making certain claims because it lacked sufficient FTC guidance). R

294. For a more detailed discussion of the FTC's recent efforts to regulate fitness advertisers and products, see *supra* notes 188-198 and accompanying text. R

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scientific research.[295] Firstly, recent consent orders suggest that the FTC should mandate that advertisers support claims with two randomized, blinded clinical trials.[296] Additionally, the FTC should require that retailers use studies that examine how products hold up in real-life situations as consumers would use the products.[297] Similarly, the Commission should encourage retailers to abide by generally understood scientific principles that increase a claim's reliability, such as ensuring that a claim is supported by more than one study yielding the desired results.[298] Finally, the FTC should strongly discourage retailers from funding research to substantiate their fitness claims because such practices can be susceptible to abuse and may easily mislead trusting consumers.[299]

The FTC certainly made a public statement regarding false and deceptive advertising when it filed the complaint against Reebok and won a $25 million settlement for purchasers of the products.[300] Monetary penalties for unsubstantiated advertising, however, may not be enough to stop similar retailers from making such claims: following the Reebok settlement, some commentators speculated that revenue from EasyTone sales more than paid for the shoes' advertising costs as well as the $25 million in mandated refunds.[301] Commentators agree that the FTC has ramped up its regulatory authority in recent years, but it remains to be seen whether the agency's efforts will be successful at ensuring that fitness advertisers have a scientific basis for their claims.[302] As large, successful retail-

295. For a more detailed discussion of the sources of the proposed fitness substantiation guidelines, see *supra* notes 237-239 and accompanying text. R

296. For a more detailed discussion of the need for two clinical trials, see *supra* notes 240-255 and accompanying text. R

297. For a more detailed discussion about testing a fitness product in "real-world conditions," see *supra* notes 256-265 and accompanying text. R

298. For a more detailed discussion about why the FTC should discourage outlier studies to substantiate fitness claims, see *supra* notes 266-276 and accompanying text. R

299. For a more detailed discussion about the FTC's need to discourage advertiser- and industry-funded studies, see *supra* notes 277-284 and accompanying text. R

300. *See generally* Martin & O'Connor, *supra* note 5, at B1 (discussing implications of toning shoe industry following Reebok settlement). R

301. *See* Chris Morran, *Reebok Spent at Least $64 Million on Deceptive EasyTone Ads*, CONSUMERIST (Sept. 28, 2011, 1:30 PM), http://consumerist.com/2011/09/reebok-spent-at-least-64-million-on-deceptive-easytone-ads.html (speculating that Reebok still made money from EasyTone sales despite high advertising costs and FTC settlement penalty).

302. *See* Lauren Williamson, *FTC Becomes More Aggressive Against False Health Claims*, INSIDE COUNSEL (Jan. 1, 2011), http://www.insidecounsel.com/2011/01/01/ftc-becomes-more-aggressive-against-false-health-claims (quoting lawyer who refers to FTC as "aggressive and strong regulator").

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ers may conclude that successful advertising outweighs the threat of federal enforcement, the FTC needs to consider a regulatory system that truly deters unsubstantiated advertising, instead of merely slapping advertisers on the wrist.[303]

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303. *See* Dana Mattioli & Maya Jackson Randall, *Reebok Stands Behind Its Claims as 'Toning' Shoe Runs Afoul of FTC*, WALL ST. J., Sept. 29, 2011, at B1, *available at* http://online.wsj.com/article/SB10001424052970204138204576598743479090706.html (evaluating implications of Reebok settlement on future FTC enforcement actions and what companies should consider in the future).

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